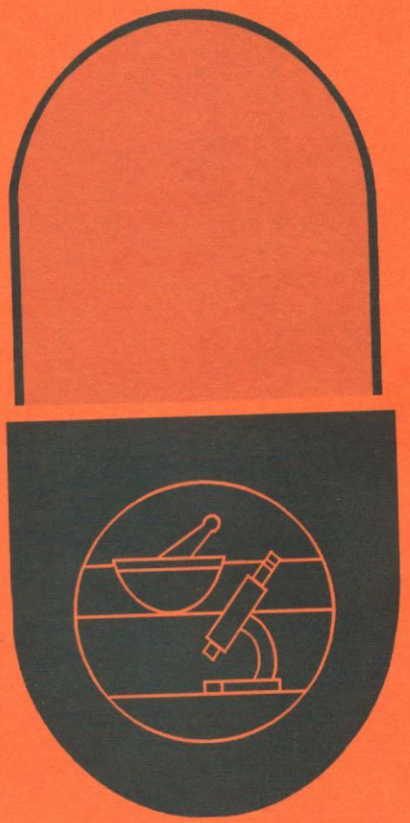
CUMULATIVE SUPPLEMENT 4

JAN'95-APR'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
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

Cumulative Supplement 4

APRIL 1995

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

CUMULATIVE SUPPLEMENT 4

APRIL 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)
BOOTS PHARMACEUTICALS INC (BOOTS)	KNOLL PHARMACEUTICAL COMPANY SUB BASF CORPORATION (KNOLL PHARM)
BRIAN PHARMACEUTICALS INC (BRIAN)	HYGENICS PHARMACEUTICALS INC (HYGENICS)
MILES PHARMACEUTICAL DIV MILES INC (MILES)	BAYER CORPORATION (BAYER)
PENNEX PHARMACEUTICALS INC (PENNEX)	MORTON GROVE PHARMACEUTICALS INC (MORTON GROVE)

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	9195		
SINGLE SOURCE	2178 (23.8%)	2186 (23.8%)		
MULTISOURCE	6963 (76.2%)	7009 (76.2%)		
THERAPEUTICALLY EQUIVALENT	6330 (69.2%)	6380 (69.4%)		
NOT THERAPEUTICALLY EQUIVALENT	453 (5.0%)	453 (4.9%)		
EXCEPTIONS[1]	180 (2.0%)	176 (1.9%)		
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	534	541		

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

PRESCRIPTION DRUG PRODUCT LIST
15TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 4 / JAN'95 - APR'95

ACEBUTOLOL HYDROCHLORIDE

CAPSULE; ORAL

> ADD >		**ACEBUTOLOL HCL**			
> ADD >	**AB**	MYLAN	**EQ 200MG BASE**	**N74288 001**	
> ADD >				APR 24, 1995	
> ADD >	**AB**		**EQ 400MG BASE**	**N74288 002**	
> ADD >				APR 24, 1995	
		SECTRAL			
> ADD >	**AB**	WYETH AYERST	**EQ 200MG BASE**	**N18917 001**	
> ADD >				DEC 28, 1984	
> ADD >	**AB** +		**EQ 400MG BASE**	**N18917 003**	
> ADD >				DEC 28, 1984	

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

		ACETAMINOPHEN AND CODEINE PHOSPHATE			
> DLT >	**AA**	MIKART	**650MG;30MG**	**N89231 001**	
> DLT >				MAR 03, 1986	
> ADD >	+		650MG;30MG	N89231 001	
> ADD >				MAR 03, 1986	
> DLT >		**PHENAPHEN-650 W/ CODEINE**			
> DLT >	**AA** +	ROBINS AH	**650MG;30MG**	**N85856 001**	
> ADD >	@		650MG;30MG	N85856 001	

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

	ANEXSIA			
AA	BOEHRINGER MANNHEIM	**500MG;5MG**	**N89160 001**	
			APR 23, 1987	
AA	KING PHARMS	**500MG;5MG**	**N89160 001**	
			APR 23, 1987	
	ANEXSIA 7.5/650			
AA	BOEHRINGER MANNHEIM	**650MG;7.5MG**	**N89725 001**	
			SEP 30, 1987	
AA	KING PHARMS	**650MG;7.5MG**	**N89725 001**	
			SEP 30, 1987	

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

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

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

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

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

		ACETYLCYSTEINE			
> DLT >	**AN**	DUPONT MERCK	**10%**	**N71364 001**	
> DLT >				MAY 01, 1989	
> DLT >	**AN**		**20%**	**N71365 001**	
> DLT >				MAY 01, 1989	
> ADD >	**AN**	FAULDING	**10%**	**N71364 001**	
> ADD >				MAY 01, 1989	
> ADD >	**AN**		**20%**	**N71365 001**	
> ADD >				MAY 01, 1989	

AMIKACIN SULFATE

INJECTABLE; INJECTION

		AMIKACIN			
> DLT >	**AP**	DUPONT MERCK	**EQ 50MG BASE/ML**	**N63350 001**	
> DLT >				JUL 30, 1993	
> DLT >	**AP**		**EQ 250MG BASE/ML**	**N63350 002**	
> DLT >				JUL 30, 1993	
> ADD >	**AP**	FAULDING	**EQ 50MG BASE/ML**	**N63350 001**	
> ADD >				JUL 30, 1993	
> ADD >	**AP**		**EQ 250MG BASE/ML**	**N63350 002**	
> ADD >				JUL 30, 1993	
		AMIKIN			
AP		APOTHECON	**EQ 50MG BASE/ML**	**N62311 001**	
AP			**EQ 250MG BASE/ML**	**N62311 002**	

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

	AMITRIPTYLINE HCL			
AB	ROXANE	**150MG**	**N86090 001**	
@		150MG	N86090 001	

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL
LOTREL

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

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

> ADD >	**AB**	CONSOLIDATED PHARM	**250MG**	**N62058 001**
> ADD >	**AB**		**500MG**	**N62058 002**
> DLT >		**COMOX**		
> DLT >	**AB**	COPANOS	**250MG**	**N62058 001**
> DLT >	**AB**		**500MG**	**N62058 002**

POWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN

> ADD >	**AB**	CONSOLIDATED PHARM	**125MG/5ML**	**N62059 001**
> ADD >	**AB**		**250MG/5ML**	**N62059 002**
> DLT >		**AMOXICILLIN TRIHYDRATE**		
> DLT >	**AB**	COPANOS	**125MG/5ML**	**N62059 001**
> DLT >	**AB**		**250MG/5ML**	**N62059 002**

AMPHOTERICIN B

INJECTABLE; INJECTION
AMPHOTERICIN B

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

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM

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

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM

@	COPANOS	EQ 250MG BASE/VIAL	N61936 001
@		EQ 500MG BASE/VIAL	N61936 002
@		EQ 1GM BASE/VIAL	N61936 003
@		EQ 2GM BASE/VIAL	N61936 004

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
AMPICILLIN TRIHYDRATE

> ADD >	**AB**	CONSOLIDATED PHARM	**EQ 250MG BASE**	**N61602 001**
> ADD >	**AB**		**EQ 500MG BASE**	**N61602 002**
> DLT >	**AB**	COPANOS	**EQ 250MG BASE**	**N61602 001**
> DLT >	**AB**		**EQ 500MG BASE**	**N61602 002**

POWDER FOR RECONSTITUTION; ORAL
AMPICILLIN TRIHYDRATE

> ADD >	**AB**	CONSOLIDATED PHARM	**EQ 125MG BASE/5ML**	**N61601 001**
> ADD >	**AB**		**EQ 250MG BASE/5ML**	**N61601 002**
> DLT >	**AB**	COPANOS	**EQ 125MG BASE/5ML**	**N61601 001**
> DLT >	**AB**		**EQ 250MG BASE/5ML**	**N61601 002**

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
AB		**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

ATENOLOL

TABLET; ORAL
ATENOLOL

AB	MARTEC	**100MG**	**N74127 002**	FEB 21, 1995

ATOVAQUONE

SUSPENSION; ORAL
MEPRON

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

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION
AZATHIOPRINE SODIUM

AP	BEDFORD	**EQ 100MG BASE/VIAL**	**N74419 001**	MAR 31, 1995

IMURAN

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**	

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLOL

> DLT > **AP**	DUPONT MERCK	**50MG/ML**	**N17954 001**	
> ADD > **AP**	FAULDING	**50MG/ML**	**N17954 001**	

BUMETANIDE

INJECTABLE; INJECTION
BUMETANIDE

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

TABLET; ORAL
BUMETANIDE

> ADD > **AB**	ZENITH LABS	**0.5MG**	**N74225 001**	APR 24, 1995
> ADD > **AB**		**1MG**	**N74225 002**	APR 24, 1995
> ADD > **AB**		**2MG**	**N74225 003**	APR 24, 1995

BUMEX

> ADD > **AB**	ROCHE	**0.5MG**	**N18225 002**	FEB 28, 1983
> ADD > **AB**		**1MG**	**N18225 001**	FEB 28, 1983
> ADD > **AB** +		**2MG**	**N18225 003**	JUN 14, 1985

CALCITONIN, SALMON

INJECTABLE; INJECTION
CALCITONIN-SALMON

> ADD > **AP**	ASTRA	**200 IU/ML**	**N73690 001**	APR 14, 1995

CAPTOPRIL

TABLET; ORAL
CAPOTEN

AB	BRISTOL MYERS SQUIBB	**12.5MG**	**N18343 005**	JAN 17, 1985
AB		**25MG**	**N18343 002**	
AB		**50MG**	**N18343 001**	
AB +		**100MG**	**N18343 003**	

CAPTOPRIL

AB	APOTHECON	**12.5MG**	**N74472 001**	MAR 31, 1995
AB		**25MG**	**N74472 002**	MAR 31, 1995
AB		**50MG**	**N74472 003**	MAR 31, 1995

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

	AB	APOTHECON	100MG	N74472 004	MAR 31, 1995

CARBACHOL

SOLUTION; INTRAOCULAR
CARBASTAT

> ADD >					
> ADD >	AT	CIBA	0.01%	N73677 001	APR 28, 1995
> ADD >					

MIOSTAT

> ADD >	AT	+ ALCON	0.01%	N16968 001	

CEFACLOR

CAPSULE; ORAL
CECLOR

> ADD >	AB	+ LILLY	EQ 250MG BASE	N50521 001	
> ADD >	AB		EQ 250MG BASE	N62205 001	
> ADD >	AB	+	EQ 500MG BASE	N50521 002	
> ADD >	AB		EQ 500MG BASE	N62205 002	
> ADD >					

CEFACLOR

> ADD >	AB	LEDERLE	EQ 250MG BASE	N64107 001	APR 27, 1995
> ADD >					
> ADD >	AB		EQ 500MG BASE	N64107 002	APR 27, 1995
> ADD >					
> ADD >	AB	ZENITH LABS	EQ 250MG BASE	N64061 001	APR 27, 1995
> ADD >					
> ADD >	AB		EQ 500MG BASE	N64061 002	APR 27, 1995
> ADD >					

POWDER FOR RECONSTITUTION; ORAL
CECLOR

> ADD >	AB	+ LILLY	EQ 125MG BASE/5ML	N50522 001	
> ADD >	AB		EQ 125MG BASE/5ML	N62206 001	
> ADD >	AB	+	EQ 187MG BASE/5ML	N62206 003	APR 20, 1988
> ADD >					
> ADD >	AB	+	EQ 250MG BASE/5ML	N50522 002	
> ADD >	AB		EQ 250MG BASE/5ML	N62206 002	
> ADD >	AB	+	EQ 375MG BASE/5ML	N62206 004	APR 20, 1988
> ADD >					

CEFACLOR

> ADD >	AB	LEDERLE	EQ 125MG BASE/5ML	N64114 001	APR 28, 1995
> ADD >					

CEFACLOR

POWDER FOR RECONSTITUTION; ORAL
CEFACLOR

> ADD >					
> ADD >	AB	LEDERLE	EQ 187MG BASE/5ML	N64115 001	APR 28, 1995
> ADD >					
> ADD >	AB		EQ 250MG BASE/5ML	N64116 001	APR 28, 1995
> ADD >					
> ADD >	AB		EQ 375MG BASE/5ML	N64110 001	APR 28, 1995
> ADD >					
> ADD >	AB	ZENITH LABS	EQ 125MG BASE/5ML	N64087 001	APR 28, 1995
> ADD >					
> ADD >	AB		EQ 187MG BASE/5ML	N64086 001	APR 28, 1995
> ADD >					
> ADD >	AB		EQ 250MG BASE/5ML	N64085 001	APR 28, 1995
> ADD >					
> ADD >	AB		EQ 375MG BASE/5ML	N64070 001	APR 28, 1995
> ADD >					

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

> DLT >	AP	ELKINS SINN	EQ 250MG BASE/VIAL	N62807 001	JAN 12, 1988
> DLT >					
> DLT >	AP		EQ 500MG BASE/VIAL	N62807 002	JAN 12, 1988
> DLT >					
> DLT >	AP		EQ 1GM BASE/VIAL	N62807 003	JAN 12, 1988
> DLT >					
> DLT >	AP		EQ 5GM BASE/VIAL	N62807 004	JAN 12, 1988
> DLT >					
> DLT >	AP		EQ 10GM BASE/VIAL	N62807 005	JAN 12, 1988
> DLT >					
> DLT >	AP		EQ 20GM BASE/VIAL	N62807 006	JAN 12, 1988
> DLT >					
> ADD >		@	EQ 250MG BASE/VIAL	N62807 001	JAN 12, 1988
> ADD >					
> ADD >		@	EQ 500MG BASE/VIAL	N62807 002	JAN 12, 1988
> ADD >					
> ADD >		@	EQ 1GM BASE/VIAL	N62807 003	JAN 12, 1988
> ADD >					
> ADD >		@	EQ 5GM BASE/VIAL	N62807 004	JAN 12, 1988
> ADD >					
> ADD >		@	EQ 10GM BASE/VIAL	N62807 005	JAN 12, 1988
> ADD >					
> ADD >		@	EQ 20GM BASE/VIAL	N62807 006	JAN 12, 1988
> ADD >					

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION
CEFOBID
PFIZER — EQ 1GM BASE/VIAL — N63333 001 MAR 31, 1995
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
@ — EQ 40MG BASE/ML — N50581 001 SEP 20, 1984

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN
AP + ROCHE — **EQ 250MG BASE/VIAL** — **N50585 001 DEC 21, 1984**
AP + — **EQ 500MG BASE/VIAL** — **N50585 002 DEC 21, 1984**
AP + — **EQ 1GM BASE/VIAL** — **N50585 003 DEC 21, 1984**
+ — EQ 250MG BASE/VIAL — N50585 001 DEC 21, 1984
+ — EQ 500MG BASE/VIAL — N50585 002 DEC 21, 1984
+ — EQ 1GM BASE/VIAL — N50585 003 DEC 21, 1984

CHLORAMPHENICOL

CAPSULE; ORAL
MYCHEL
> ADD > **AB** ARMENPHARM — **250MG** — **N60851 001**
> DLT > **AB** RACHELLE — **250MG** — **N60851 001**

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION
CHLORPHENIRAMINE MALEATE
AP STERIS — **10MG/ML** — **N83593 001**
@ — 10MG/ML — N83593 001

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL
AP STERIS — **25MG/ML** — **N85591 001**
@ — 25MG/ML — N85591 001

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE
AB LEMMON — **100MG** — **N88768 001 OCT 11, 1984**
@ — 100MG — N88768 001 OCT 11, 1984

GLUCAMIDE
AB LEMMON — **250MG** — **N88641 001 OCT 11, 1984**
@ — 250MG — N88641 001 OCT 11, 1984

CHOLESTYRAMINE

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

BAR, CHEWABLE; ORAL
CHOLYBAR
+ PARKE DAVIS — EQ 4GM RESIN/BAR — N71621 001 MAY 26, 1988
EQ 4GM RESIN/BAR — N71739 001 MAY 26, 1988
@ — EQ 4GM RESIN/BAR — N71621 001 MAY 26, 1988
@ — EQ 4GM RESIN/BAR — N71739 001 MAY 26, 1988

TABLET; ORAL
QUESTRAN
+ BRISTOL MYERS SQUIBB — EQ 1GM RESIN — N73403 001 APR 28, 1994

CHOLESTYRAMINE

TABLET; ORAL
QUESTRAN
@ BRISTOL MYERS SQUIBB 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
AP		EQ 300MG BASE/2ML	N74345 001 JAN 31, 1995
AP		EQ 300MG BASE/2ML	N74422 001 JAN 31, 1995

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL
CLEOCIN
UPJOHN — EQ 1% BASE — N50537 002 FEB 22, 1994

CLINDAMYCIN PHOSPHATE

SWAB; TOPICAL
CLEOCIN
UPJOHN — EQ 1% BASE — N50537 002 FEB 22, 1994

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL
EMBELINE
AB DPT — 0.05% — N74221 001 MAR 31, 1995

CLOTRIMAZOLE

SOLUTION; TOPICAL
CLOTRIMAZOLE
AT LEMMON — 1% — N73306 001 FEB 28, 1995

CORTICOTROPIN

INJECTABLE; INJECTION
ACTH

>DLT> AP	PARKE DAVIS	40 UNITS/VIAL	N08317 004
>ADD>	@	40 UNITS/VIAL	N08317 004

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

CYANOCOBALAMIN

INJECTABLE; INJECTION

	RUBRAMIN PC			
	@ SQUIBB	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

INJECTABLE; INJECTION

	DDAVP			
> ADD >	+ RHONE POULENC RORER	0.015MG/ML	N18938 002	> DLT >
> ADD >			APR 25, 1995	> DLT >
				> ADD >
				> ADD >

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	
	@	0.15MG;0.03MG	N20071 001	
			DEC 10, 1992	
	ORTHO-CEPT			
AB	**JOHNSON RW**	**0.15MG;0.03MG**	**N20301 001**	
			DEC 14, 1992	
		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	

DEXTROSE

INJECTABLE; INJECTION

	DEXTROSE 2.5% IN PLASTIC CONTAINER			
	MCGAW	**2.5GM/100ML**	**N19626 001**	> DLT >
			FEB 02, 1988	> DLT >
	@	2.5GM/100ML	N19626 001	> ADD >
			FEB 02, 1988	> ADD >
	DEXTROSE 7.7% IN PLASTIC CONTAINER			> DLT >
	MCGAW	**7.7GM/100ML**	**N19626 003**	> DLT >
			FEB 02, 1988	> DLT >
	@	7.7GM/100ML	N19626 003	> ADD >
			FEB 02, 1988	> ADD >

DIAZEPAM

INJECTABLE; INJECTION

	DIAZEPAM			
AP	**FUJISAWA**	**5MG/ML**	**N70662 001**	
			JUN 25, 1986	
	@	5MG/ML	N70662 001	
			JUN 25, 1986	

DICLOFENAC POTASSIUM

TABLET; ORAL

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

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

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

DIMENHYDRINATE

INJECTABLE; INJECTION
DIMENHYDRINATE

AP	STERIS	50MG/ML	N83531 001
@		50MG/ML	N83531 001

DINOPROSTONE

INSERT, EXTENDED RELEASE; VAGINAL
CERVIDIL

+	CONTROLLED THERAP	10MG	N20411 001
			MAR 30, 1995

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	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
INTROPIN

> DLT >	AP	+ DUPONT MERCK	40MG/ML	N17395 001	
> DLT >	AP	+	80MG/ML	N17395 002	
> DLT >	AP	+	160MG/ML	N17395 003	
> ADD >	AP	+ FAULDING	40MG/ML	N17395 001	
> ADD >	AP	+	80MG/ML	N17395 002	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
INTROPIN

> ADD >	AP	+ FAULDING	160MG/ML	N17395 003	

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DOXORUBICIN HCL

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

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

> DLT >	AB	PVT FORM	EQ 50MG BASE	N62631 001
> DLT >				JUL 24, 1986
> DLT >	AB		EQ 100MG BASE	N62631 002
> DLT >				JUL 24, 1986
> ADD >	@		EQ 50MG BASE	N62631 001
> ADD >				JUL 24, 1986
> ADD >	@		EQ 100MG BASE	N62631 002
> ADD >				JUL 24, 1986

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL

> DLT >	AP	DUPONT MERCK	2.5MG/ML	N71645 001
> DLT >				APR 07, 1988
> ADD >	AP	FAULDING	2.5MG/ML	N71645 001
> ADD >				APR 07, 1988

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL
ERYC

> DLT >	AB	+ PARKE DAVIS	250MG	N62338 001	
> DLT >	AB		250MG	N62618 001	
> DLT >				SEP 25, 1985	

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

		ERYC			
> ADD >	AB	+ PARKE DAVIS	250MG	N62618 001	
> ADD				SEP 25, 1985	
> ADD >		@	250MG	N62338 001	

TABLET, DELAYED RELEASE; ORAL

		ROBIMYCIN			
> DLT >					
> DLT >	AB	ROBINS AH	250MG	N61633 001	
> ADD >		@	250MG	N61633 001	

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

		WYAMYCIN E			
> DLT >					
> DLT >	AB	WYETH AYERST	EQ 200MG BASE/5ML	N62123 002	
> DLT >	AB		EQ 400MG BASE/5ML	N62123 001	
> ADD >		@	EQ 200MG BASE/5ML	N62123 002	
> ADD >		@	EQ 400MG BASE/5ML	N62123 001	

ERYTHROMYCIN STEARATE

TABLET; ORAL

		ETHRIL 250			
> DLT >					
> DLT >	AB	SQUIBB	EQ 250MG BASE	N61605 001	
> ADD >		@	EQ 250MG BASE	N61605 001	
> DLT >		ETHRIL 500			
> DLT >	AB	SQUIBB	EQ 500MG BASE	N61605 002	
> ADD >		@	EQ 500MG BASE	N61605 002	

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	
BX		NOVEN	0.05MG/24HR	N20323 002	
				OCT 28, 1994	

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

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

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

		OVCON-35			
> ADD >		+ BRISTOL MYERS SQUIBB	0.035MG;0.4MG	N18127 001	
> DLT >		+ MEAD JOHNSON	0.035MG;0.4MG	N18127 001	
> DLT >		OVCON-50			
> ADD >		@ BRISTOL MYERS SQUIBB	0.05MG;1MG	N18128 001	
> DLT >		+ MEAD JOHNSON	0.05MG;1MG	N18128 001	

TABLET; ORAL-28

		OVCON-35			
> ADD >		BRISTOL MYERS SQUIBB	0.035MG;0.4MG	N17716 001	
> DLT >		MEAD JOHNSON	0.035MG;0.4MG	N17716 001	
		OVCON-50			
> ADD >		BRISTOL MYERS SQUIBB	0.05MG;1MG	N17576 001	
> DLT >		MEAD JOHNSON	0.05MG;1MG	N17576 001	

ETOPOSIDE

INJECTABLE; INJECTION

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

FENOFIBRATE

CAPSULE; ORAL

		LIPIDIL			
		+ LABS FOURNIER	100MG	N19304 001	
				DEC 31, 1993	
		@	100MG	N19304 001	
				DEC 31, 1993	

FLUNISOLIDE

SPRAY, METERED; NASAL

NASALIDE

BX	+ SYNTEX	0.025MG/INH	N18148 001	

NASAREL

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

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUOCINOLONE ACETONIDE

AT	+ HAMILTON PHARMA CA	**0.01%**	**N12787 004**	
AT	+	**0.025%**	**N12787 002**	
> ADD > **AT**	+	**0.025%**	**N12787 005**	
> ADD >	+	0.2%	N16161 002	

SYNALAR

AT	+ SYNTEX	**0.01%**	**N12787 004**	
AT	+	**0.025%**	**N12787 002**	

> DLT > SYNALAR-HP

> DLT >	+ SYNTEX	0.2%	N16161 002	

> DLT > **SYNEMOL**

> DLT > **AT**	+ SYNTEX	**0.025%**	**N12787 005**	

OINTMENT; TOPICAL

FLUOCINOLONE ACETONIDE

AT	+ HAMILTON PHARMA CA	**0.025%**	**N13960 001**	

SYNALAR

AT	+ SYNTEX	**0.025%**	**N13960 001**	

SOLUTION; TOPICAL

FLUOCINOLONE ACETONIDE

> ADD > **AT**	+ HAMILTON PHARMA CA	**0.01%**	**N15296 001**	

> DLT > **SYNALAR**

> DLT > **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**	

FLUOCINONIDE

GEL; TOPICAL

FLUOCINONIDE

> ADD > **AB**	+ HAMILTON PHARMA CA	**0.05%**	**N17373 001**	

> DLT > **LIDEX**

> DLT > **AB**	+ SYNTEX	**0.05%**	**N17373 001**	

OINTMENT; TOPICAL

FLUOCINONIDE

> ADD > **AB**	+ HAMILTON PHARMA CA	**0.05%**	**N16909 002**	

> DLT > **LIDEX**

> DLT > **AB**	+ SYNTEX	**0.05%**	**N16909 002**	

SOLUTION; TOPICAL

FLUOCINONIDE

AT	FOUGERA	**0.05%**	**N72934 001** FEB 27, 1995	
AT	+ HAMILTON PHARMA CA	**0.05%**	**N18849 001** APR 06, 1984	

LIDEX

AT	+ SYNTEX	**0.05%**	**N18849 001** 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

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

GEMFIBROZIL

CAPSULE; ORAL

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

TABLET; ORAL

		GEMFIBROZIL		
> ADD >	**AB**	CHELSEA LABS	**600MG**	**N74442 001 APR 28, 1995**
> ADD >	**AB**	MYLAN	**600MG**	**N74452 001 FEB 16, 1995**

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

		GENTAMICIN SULFATE		
> ADD >	**AT**	ALCON	**EQ 0.3% BASE**	**N62196 001**

GLIPIZIDE

TABLET; ORAL

		GLIPIZIDE		
> ADD >	**AB**	GENEVA PHARMS	**5MG**	**N74305 001 APR 07, 1995**
> ADD >	**AB**		**10MG**	**N74305 002 APR 07, 1995**
> ADD >	**AB**	WATSON LABS	**5MG**	**N74223 001 FEB 27, 1995**
> ADD >	**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

GUANABENZ ACETATE

TABLET; ORAL

		GUANABENZ ACETATE		
> ADD >	**AB**	ZENITH LABS	**EQ 4MG BASE**	**N74149 001 APR 07, 1995**
> ADD >	**AB**		**EQ 8MG BASE**	**N74149 002 APR 07, 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

HEPARIN SODIUM

> DLT >	AP	+	ABBOTT	2,500 UNITS/ML	N05264 014 APR 07, 1986
> DLT >		+		2,000 UNITS/ML	N05264 013 APR 07, 1986
> DLT >	AP		ELKINS SINN	10,000 UNITS/ML	N17037 013 APR 07, 1986
> ADD >	AP			5,000 UNITS/0.5ML	N17037 013 APR 07, 1986
> DLT >	AP		PHARMA SERVE NY	1,000 UNITS/ML	N86129 001
> DLT >	AP		WYETH AYERST	2,500 UNITS/ML	N17007 007
> ADD >	AP	+		2,500 UNITS/ML	N17007 007

HEPARIN SODIUM PRESERVATIVE FREE

> ADD >	AP	+	ABBOTT	2,500 UNITS/ML	N05264 014 APR 07, 1986
> ADD >		+		2,000 UNITS/ML	N05264 013 APR 07, 1986
> DLT >	AP		FUJISAWA	1,000 UNITS/ML	N17029 010 APR 28, 1986
> ADD >	AP	+		1,000 UNITS/ML	N17029 010 APR 28, 1986
> ADD >	AP		PHARMA SERVE NY	1,000 UNITS/ML	N86129 001
> DLT >	AP		STERLING WINTHROP	10,000 UNITS/ML	N89522 001 MAY 04, 1987
> ADD >	AP	+		10,000 UNITS/ML	N89522 001 MAY 04, 1987

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
APRESOLINE-ESIDRIX

	+	CIBA	25MG;15MG	N12026 002

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
APRESOLINE-ESIDRIX

	@	CIBA	25MG;15MG	N12026 002

> ADD > HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

> ADD > TABLET; ORAL
> ADD > HYZAAR
> ADD > + MERCK 12.5MG;50MG N20387 001
> ADD > APR 28, 1995

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

HYDROCORTISONE

ENEMA; RECTAL

	CORTENEMA			
+	SOLVAY	100MG/60ML	N16199 001	DLT

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

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

KANAMYCIN SULFATE

INJECTABLE; INJECTION

	KANAMYCIN			
AP	ELKINS SINN	EQ 75MG BASE/2ML	N62324 001	DLT
AP		EQ 500MG BASE/2ML	N62324 002	DLT
AP		EQ 1GM BASE/3ML	N62324 003	DLT
@		EQ 75MG BASE/2ML	N62324 001	ADD
@		EQ 500MG BASE/2ML	N62324 002	ADD
@		EQ 1GM BASE/3ML	N62324 003	ADD

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		
AB	MERCK	2.5MG	N19558 006 JAN 28, 1994
		2.5MG	N19558 006 JAN 28, 1994
	ZESTRIL		
AB	ZENECA	2.5MG	N19777 005 APR 29, 1993
@		2.5MG	N19777 005 APR 29, 1993

LITHIUM CARBONATE

TABLET; ORAL

		LITHOTABS			
> DLT >	**AB**	SOLVAY	**300MG**	**N16980 001**	
> ADD >	**AB**	+	**300MG**	**N16980 001**	

> ADD > LOSARTAN POTASSIUM

> ADD > TABLET; ORAL

> ADD >		COZAAR			
> ADD >		MERCK	25MG	N20386 001	APR 14, 1995
> ADD >					
> ADD >		+	50MG	N20386 002	APR 14, 1995
> ADD >					

MEBENDAZOLE

TABLET, CHEWABLE; ORAL

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

MEGESTROL ACETATE

TABLET; ORAL

		MEGACE			
> ADD >	**AB**	BRISTOL MYERS SQUIBB	**20MG**	**N16979 001**	
> ADD >	**AB**	+	**40MG**	**N16979 002**	
> DLT >	**AB**	MEAD JOHNSON	**20MG**	**N16979 001**	
> DLT >	**AB**	+	**40MG**	**N16979 002**	

METFORMIN HYDROCHLORIDE

TABLET; ORAL

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

METFORMIN HYDROCHLORIDE

TABLET; ORAL

		GLUCOPHAGE			
		+ LIPHA	850MG	N20357 002	DEC 29, 1994

METHADONE HYDROCHLORIDE

POWDER; FOR RX COMPOUNDING

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

TABLET, DISPERSIBLE; ORAL

		METHADONE HCL			
> ADD >	**AA**	ROXANE	**40MG**	**N74081 001**	APR 28, 1995
> ADD >					

METHOTRIMEPRAZINE

INJECTABLE; INJECTION

		LEVOPROME			
		+ IMMUNEX	20MG/ML	N15865 001	
		+ LEDERLE	20MG/ML	N15865 001	

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION

		METHYLDOPATE HCL			
> DLT >	**AP**	DUPONT MERCK	**50MG/ML**	**N70691 001**	JUN 19, 1987
> DLT >					
> DLT >	**AP**		**50MG/ML**	**N70849 001**	JUN 19, 1987
> DLT >					
> ADD >	**AP**	FAULDING	**50MG/ML**	**N70691 001**	JUN 19, 1987
> ADD >					
> ADD >	**AP**		**50MG/ML**	**N70849 001**	JUN 19, 1987
> ADD >					

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

		METOCLOPRAMIDE HCL			
> DLT >	**AP**	DUPONT MERCK	**EQ 10MG BASE/2ML**	**N70847 001**	NOV 07, 1988
> DLT >					

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

> DLT >	**AP**	DUPONT MERCK	**EQ 10MG BASE/2ML**	**N71291 001**
> DLT				**MAR 03, 1989**
> ADD >	**AP**	FAULDING	**EQ 10MG BASE/2ML**	**N70847 001**
> ADD >				NOV 07, 1988
> ADD >	**AP**		**EQ 10MG BASE/2ML**	**N71291 001**
> ADD >				MAR 03, 1989

METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE

	AB	LEMMON	**50MG**	**N74141 001**
				JAN 31, 1995
	AB		**100MG**	**N74141 002**
				JAN 31, 1995
> ADD >	**AB**	PAR PHARM	**50MG**	**N74453 001**
> ADD >				APR 27, 1995
> ADD >	**AB**		**100MG**	**N74453 002**
> ADD >				APR 27, 1995

METYRAPONE

TABLET; ORAL
METOPIRONE

+	CIBA	**250MG**	**N12911 001**
@		250MG	N12911 001

MITOMYCIN

INJECTABLE; INJECTION
MITOMYCIN

> ADD >				
> ADD >	**AP**	CETUS BEN VENUE	**5MG/VIAL**	**N64117 001**
> ADD >				APR 19, 1995
> ADD >	**AP**		**20MG/VIAL**	**N64117 002**
> ADD >				APR 19, 1995

> ADD > MOEXIPRIL HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > UNIVASC

> ADD >	SPKU	7.5MG	N20312 001
> ADD >			APR 19, 1995

> ADD > MOEXIPRIL HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > UNIVASC

> ADD >	+ SPKU	15MG	N20312 002
> ADD >			APR 19, 1995

> ADD > NALMEFENE HYDROCHLORIDE

> ADD > INJECTABLE; INJECTION
> ADD > REVEX

> ADD >	OHMEDA	EQ 0.1MG BASE/ML	N20459 001
> ADD >			APR 17, 1995
> ADD >	+	EQ 1MG BASE/ML	N20459 002
> ADD >			APR 17, 1995

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
> ADD > **AB**	MOVA	**250MG**	**N74410 001**
> ADD >			APR 28, 1995
> ADD > **AB**		**375MG**	**N74410 002**
> ADD >			APR 28, 1995
> ADD > **AB**		**500MG**	**N74410 003**
> ADD >			APR 28, 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

AB	PUREPAC PHARM	**EQ 250MG BASE**	**N74319 001**
			MAR 20, 1995

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM

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

NEOMYCIN SULFATE

TABLET; ORAL
NEOMYCIN SULFATE

>DLT>	**AA**	BIOCRAFT	**EQ 350MG BASE**	**N60304 001**	
>ADD>			EQ 350MG BASE	N60304 001	
>DLT>	**AA**	LILLY	**EQ 350MG BASE**	**N60385 001**	
>ADD>		@	EQ 350MG BASE	N60385 001	

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

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL
NISOCOR

+	MILES	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

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

FILM, EXTENDED RELEASE; TRANSDERMAL
NITRO-DUR

+	KEY PHARMS	0.1MG/HR	N20145 001 APR 04, 1995
+		0.2MG/HR	N20145 002 APR 04, 1995
+		0.3MG/HR	N20145 003 APR 04, 1995
+		0.4MG/HR	N20145 004 APR 04, 1995
+		0.6MG/HR	N20145 005 APR 04, 1995
+		0.8MG/HR	N20145 006 APR 04, 1995

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

TRIDIL

>DLT> **AP**	DUPONT MERCK	**5MG/ML**	**N18537 001**	

NITROGLYCERIN

INJECTABLE; INJECTION

		TRIDIL			
> DLT >	+	DUPONT MERCK	0.5MG/ML	N18537 002	
> DLT >				JUN 16, 1983	
> ADD >	AP	FAULDING	5MG/ML	N18537 001	
> ADD >	+		0.5MG/ML	N18537 002	
> ADD >				JUN 16, 1983	

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

		NORTRIPTYLINE HCL			
AB		LEMMON	EQ 10MG BASE	N74132 001	
				MAR 27, 1995	
AB			EQ 25MG BASE	N74132 002	
				MAR 27, 1995	
AB			EQ 50MG BASE	N74132 003	
				MAR 27, 1995	
AB			EQ 75MG BASE	N74132 004	
				MAR 27, 1995	

NYSTATIN; TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

		NYSTATIN AND TRIAMCINOLONE ACETONIDE			
AT		PHARMAFAIR	100,000 UNITS/GM;0.1%	N62656 001	
				JUL 30, 1986	
	@		100,000 UNITS/GM;0.1%	N62656 001	
				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			
		@	CONSOLIDATED PHARM	500,000 UNITS/VIAL		N60806 001
		@		1,000,000 UNITS/VIAL		N60806 002
		@		5,000,000 UNITS/VIAL		N60806 003
		@		10,000,000 UNITS/VIAL		N60806 004
		@	COPANOS	500,000 UNITS/VIAL		N60806 001
		@		1,000,000 UNITS/VIAL		N60806 002
		@		5,000,000 UNITS/VIAL		N60806 003
		@		10,000,000 UNITS/VIAL		N60806 004
> DLT >	AP	+	LILLY	1,000,000 UNITS/VIAL		N60384 002
> DLT >	AP	+		5,000,000 UNITS/VIAL		N60384 001
> DLT >	AP	+		20,000,000 UNITS/VIAL		N60384 005
> DLT >	AP			20,000,000 UNITS/VIAL		N60601 001
> DLT >		+		200,000 UNITS/VIAL		N60384 004
> DLT >		+		500,000 UNITS/VIAL		N60384 003
> ADD >		@		200,000 UNITS/VIAL		N60384 004
> ADD >		@		500,000 UNITS/VIAL		N60384 003
> ADD >		@		1,000,000 UNITS/VIAL		N60384 002
> ADD >		@		5,000,000 UNITS/VIAL		N60384 001
> ADD >		@		20,000,000 UNITS/VIAL		N60384 005
> ADD >		@		20,000,000 UNITS/VIAL		N60601 001
			PFIZERPEN			
> DLT >	AP		PFIZER	1,000,000 UNITS/VIAL		N60657 001
> ADD >	AP	+		1,000,000 UNITS/VIAL		N60657 001
> DLT >	AP			5,000,000 UNITS/VIAL		N60657 002
> ADD >	AP	+		5,000,000 UNITS/VIAL		N60657 002
> DLT >	AP			20,000,000 UNITS/VIAL		N60657 003
> ADD >	AP	+		20,000,000 UNITS/VIAL		N60657 003

TABLET; ORAL

		PENICILLIN G POTASSIUM			
> DLT >	AB	DISTA	250,000 UNITS		N60403 001
> ADD >		@ LILLY	250,000 UNITS		N60403 001

PENICILLIN G PROCAINE

INJECTABLE; INJECTION

	PENICILLIN G PROCAINE		
@	CONSOLIDATED PHARM	300,000 UNITS/ML	N60800 001
@		600,000 UNITS/1.2ML	N60800 002
@	COPANOS	300,000 UNITS/ML	N60800 001
@		600,000 UNITS/1.2ML	N60800 002

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN V POTASSIUM

> ADD >	**AA**	CONSOLIDATED PHARM	**EQ 125MG BASE/5ML**	**N61529 001**	
> ADD >	**AA**		**EQ 250MG BASE/5ML**	**N61529 002**	
> DLT >	**AA**	COPANOS	**EQ 125MG BASE/5ML**	**N61529 001**	
> DLT >	**AA**		**EQ 250MG BASE/5ML**	**N61529 002**	

TABLET; ORAL
PENICILLIN V POTASSIUM

> ADD >	**AB**	CONSOLIDATED PHARM	**EQ 250MG BASE**	**N61528 001**	
> ADD >	**AB**		**EQ 500MG BASE**	**N61528 002**	
> DLT >	**AB**	COPANOS	**EQ 250MG BASE**	**N61528 001**	
> DLT >	**AB**		**EQ 500MG BASE**	**N61528 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	> DLT >
+		EQ 30MG BASE	N11613 002	> DLT >
	IONAMIN-15			
	FISONS	EQ 15MG BASE	N11613 004	> ADD >
	IONAMIN-30			
+	FISONS	EQ 30MG BASE	N11613 002	> ADD >

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

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

POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
MINIZIDE

	PFIZER	0.5MG;1MG	N17986 001	> DLT >
		0.5MG;2MG	N17986 002	> DLT >
+		0.5MG;5MG	N17986 003	> DLT >
		0.5MG;EQ 1MG BASE	N17986 001	> ADD >
		0.5MG;EQ 2MG BASE	N17986 002	> ADD >
+		0.5MG;EQ 5MG BASE	N17986 003	> ADD >

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL
KAON CL

	SAVAGE LABS	6.7MEQ	N17046 001
@		6.7MEQ	N17046 001

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL
KAON CL-10

BC		SAVAGE LABS	10MEQ	N17046 002
	@		10MEQ	N17046 002

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
HYDELTRASOL

AP	+	MERCK SHARP DOHME	**EQ 20MG PHOSPHATE/ML**	**N11583 002**
	+		EQ 20MG PHOSPHATE/ML	N11583 002

PREDNISOLONE SODIUM PHOSPHATE

AP		STERIS	**EQ 20MG PHOSPHATE/ML**	**N80517 001**
	@		EQ 20MG PHOSPHATE/ML	N80517 001

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCAN SR

AB		PARKE DAVIS	**250MG**	**N86468 001**
	@		250MG	N86468 001

PROPANTHELINE BROMIDE

TABLET; ORAL
PROPANTHELINE BROMIDE

> DLT >	**AA**		DANBURY PHARMA	**15MG**	**N83029 002**
> ADD >		@		15MG	N83029 002
> DLT >	**AA**		GLOBAL PHARMS	**15MG**	**N84541 002**
> ADD >		@		15MG	N84541 002
> DLT >	**AA**		TABLICAPS	**15MG**	**N84428 001**
> ADD >		@		15MG	N84428 001

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

BD		LILLY	50MG	N06213 001
	@		50MG	N06213 001

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM

AA		ZENITH LABS	**100MG**	**N85869 001**
	@		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

STREPTOMYCIN SULFATE

INJECTABLE; INJECTION
STREPTOMYCIN SULFATE

> DLT >	**AP**		LILLY	**EQ 1GM BASE/VIAL**	**N60107 001**
> DLT >	**AP**			**EQ 5GM BASE/VIAL**	**N60107 002**
> DLT >				**EQ 1GM BASE/2ML**	**N60404 001**
> ADD >		@		EQ 1GM BASE/2ML	N60404 001
> ADD >		@		EQ 1GM BASE/VIAL	N60107 001
> ADD >		@		EQ 5GM BASE/VIAL	N60107 002
> DLT >	**AP**	+	PFIZER	**EQ 1GM BASE/VIAL**	**N60076 001**
> DLT >	**AP**	+		**EQ 5GM BASE/VIAL**	**N60076 002**
> ADD >		+		EQ 1GM BASE/VIAL	N60076 001
> ADD >		+		EQ 5GM BASE/VIAL	N60076 002

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 SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL
TECHNETIUM TC 99M GENERATOR

		DUPONT	0.0083-2.7 CI/GENERATOR	N17771 001	

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL

> DLT >	AB	PVT FORM	250MG	N62686 001 JUL 24, 1986	
> DLT >	AB		500MG	N62686 002 JUL 24, 1986	
> ADD >		@	250MG	N62686 001 JUL 24, 1986	
> ADD >		@	500MG	N62686 002 JUL 24, 1986	

FIBER, EXTENDED RELEASE; PERIODONTAL
ACTISITE

> DLT >		+ ON SITE	12.7MG/FIBER	N50653 001 MAR 25, 1994	
> ADD >		+ ON SITE ALZA	12.7MG/FIBER	N50653 001 MAR 25, 1994	

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	

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL
THEOPHYLLINE

> ADD >	AB	INWOOD LABS	450MG	N40034 001 APR 28, 1995	
		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	

TIMOLOL

SOLUTION/DROPS; OPHTHALMIC
BETIMOL

	+	LEIRAS	EQ 0.25% BASE	N20439 001 MAR 31, 1995
	+		EQ 0.5% BASE	N20439 002 MAR 31, 1995

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC
TIMOLOL MALEATE

> ADD >	AT	ALCON	EQ 0.25% BASE	N74261 001 APR 28, 1995
> ADD >	AT		EQ 0.5% BASE	N74262 001 APR 28, 1995
		TIMOPTIC		
> ADD >	AT	+ MERCK	EQ 0.25% BASE	N18086 001

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC
TIMOPTIC

> ADD >	**AT**	+ MERCK	**EQ 0.5% BASE**	**N18086 002**	

TIOCONAZOLE

OINTMENT; VAGINAL
VAGISTAT-1

> ADD >		+ BRISTOL MYERS	6.5%	N19355 001	
> ADD >				DEC 30, 1986	
> DLT >		+ BRISTOL MYERS SQUIBB	6.5%	N19355 001	
> DLT >				DEC 30, 1986	

TOCAINIDE HYDROCHLORIDE

TABLET; ORAL
TONOCARD

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

TRAMADOL HYDROCHLORIDE

TABLET; ORAL
ULTRAM

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

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE IN ABSORBASE

	+	CAROLINA MEDCL	0.05%	N89595 001
				MAR 23, 1995

TRILOSTANE

CAPSULE; ORAL
MODRASTANE

> DLT >		SANOFI WINTHROP	30MG	N18719 002
> DLT >				DEC 31, 1984
> DLT >	+		60MG	N18719 001
> DLT >				DEC 31, 1984
> ADD >	@		30MG	N18719 002
> ADD >				DEC 31, 1984
> ADD >	@		60MG	N18719 001
> ADD >				DEC 31, 1984

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/6ML**	**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

CAPSULE; ORAL

	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	FEB 27, 1995
	325MG	N73107 001	FEB 27, 1995
	650MG	N73108 001	FEB 27, 1995

>ADD< FAMOTIDINE

>ADD< TABLET; ORAL
>ADD< PEPCID AC

>ADD< + MERCK	10MG	N20325 001	APR 28, 1995 >ADD<

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

>ADD< PROVEL

>ADD< + SANDOZ	200MG	N20402 001	APR 20, 1995 >ADD<

TABLET; ORAL
MIDOL

WINTHROP	200MG	N70591 001	SEP 02, 1987
	200MG	N71001 001	SEP 02, 1987
@	200MG	N70591 001	SEP 02, 1987
@	200MG	N71001 001	SEP 02, 1987

INSULIN PORK

INJECTABLE; INJECTION
INSULIN

+ NOVO NORDISK	100 UNITS/ML	N17926 003

REGULAR INSULIN

+ NOVO NORDISK	100 UNITS/ML	N17926 003

INSULIN PURIFIED PORK

INJECTABLE; INJECTION
>DLT< VELOSULIN

>DLT< NOVO NORDISK	100 UNITS/ML	N18193 001
>ADD< @	100 UNITS/ML	N18193 001

INSULIN PURIFIED PORK; INSULIN SUSP ISOPHANE PURIFIED PORK

>DLT< INJECTABLE; INJECTION
>DLT< INSULIN NORDISK MIXTARD (PORK)

>DLT< + NOVO NORDISK	30 UNITS/ML;70 UNITS/ML	N18195 001
>ADD< @	30 UNITS/ML;70 UNITS/ML	N18195 001

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 ISOPHANE PURIFIED PORK

INJECTABLE; INJECTION
>DLT< INSULIN INSULATARD NPH NORDISK

>DLT< + NOVO NORDISK	100 UNITS/ML	N18194 001
>ADD< @	100 UNITS/ML	N18194 001

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION
PROTAMINE ZINC AND ILETIN II

+ LILLY	100 UNITS/ML	N18476 001

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION

	PROTAMINE ZINC AND ILETIN II		
	@ LILLY	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

NAPROXEN SODIUM

TABLET; ORAL

	ALEVE		
>_DLT_>	HAMILTON PHARMS	EQ 200MG BASE	N20204 002
>_DLT_>			JAN 11, 1994
>_ADD_>	+	EQ 200MG BASE	N20204 002
>_ADD_>			JAN 11, 1994

NONOXYNOL-9

AEROSOL; VAGINAL

	DELFEN		
	@ ORTHO	12.5%	N14349 002

POTASSIUM IODIDE

>_DLT_>	SOLUTION; ORAL		
>_DLT_>	POTASSIUM IODIDE		
>_DLT_>	+ ROXANE	1GM/ML	N18551 001
>_DLT_>			FEB 19, 1982
>_ADD_>	@	1GM/ML	N18551 001
>_ADD_>			FEB 19, 1982

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 4 / APRIL '95

HETASTARCH 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
6% HETASTARCH IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
ABBOTT 6GM/100ML;0.9GM/100ML N74193
JAN 30, 1995

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January-April 1995]

NAME *Generic/Chemical* *TN=Trade Name*	***INDICATION DESIGNATED***	***SPONSOR & ADDRESS*** *DD=Date Designated* *MA=Marketing Approval*
ADENO-AS'TED VIRAL-BASED VECTOR CYSTIC FIBROSIS GENE THERAPY TN=	TREATMENT OF CYSTIC FIBROSIS.	TARGETED GENETICS CORPORATION 1100 OLIVE WAY, SUITE 100 SEATTLE WA 98101 DD 02/15/95 MA / /
AMINOCAPROIC ACID TN=	FOR THE TOPICAL TREATMENT OF TRAUMATIC HYPHEMA OF THE EYE.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 01/06/95 MA / /
APL 400-020 TN=	TREATMENT OF CUTANEOUS T CELL LYMPHOMA.	APOLLON, INC. ONE GREAT VALLEY PARKWAY MALVERN PA 19355 DD 03/08/95 MA / /
CHONDROITINASE TN=	TREATMENT OF PATIENTS UNDERGOING VITRECTOMY.	STORZ OPHTHALMICS AMERICAN CYANAMID COMPANY PEARL RIVER NY 10965 DD 02/09/95 MA / /
CLOTRIMIDAZOLE TN=	TREATMENT OF SICKLE CELL DISEASE.	BRUGNARA, CARLO M.D. THE CHILDREN'S HOSPITAL BOSTON MA 02115 DD 04/24/95 MA / /
CYSTIC FIBROSIS TR GENE THERAPY (RECOMBINANT ADENOVIRUS) TN= ADgvCFTR.10	TREATMENT OF CYSTIC FIBROSIS.	GENVAC, INCORPORATED 12111 PARKLAWN DRIVE ROCKVILLE MD 20852 DD 03/09/95 MA / /
GLUTAMINE TN=	FOR USE WITH HUMAN GROWTH HORMONE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE).	RESEARCH TRIANGLE PHARMACEUTICALS 4364 SOUTH ALSTON AVENUE DURHAM NC 27713 DD 03/06/95 MA / /
GLYCERYL TRIOLEATE AND GLYCERYL TRIERUCATE TN=	TREATMENT OF ADRENOLEUKODYSTROPHY.	MOSER, HUGO W. M.D. JOHNS HOPKINS UNIVERSITY BALTIMORE MD 21205 DD 02/14/95 MA / /
HEPATITIS B IMMUNE GLOBULIN, INTRAVENOUS TN= H-BIGIV	PROPHYLAXIS AGAINST HEPATITIS B VIRUS REINFECTION IN LIVER TRANSPLANT PATIENTS.	NORTH AMERICAN BIOLOGICS, INC. 16500 N.W. 15th AVENUE MIAMI FL 33169 DD 03/08/95 MA / /
HUMAN GROWTH HORMONE TN=	FOR USE WITH GLUTAMINE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE).	RESEARCH TRIANGLE PHARMACEUTICALS 4364 SOUTH ALSTON AVENUE DURHAM NC 27713 DD 03/06/95 MA / /
HUMAN IMMUNODEFICIENCY VIRUS IMMUNE GLOBULIN TN= HIVIG	TREATMENT OF HIV-INFECTED PEDIATRIC PATIENTS.	NORTH AMERICAN BIOLOGICALS, INC. 16500 N.W. 15TH AVENUE MIAMI FL 33169 DD 01/04/95 MA / /
PHENYLALANINE AMMONIA-LYASE TN= PHENYLASE	TREATMENT OF HYPERPHENYLALANINEMIA.	IBEX TECHNOLOGIES, INC. 5485 PARE MONTREAL, QUEBEC DD 03/08/95 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME *Generic/Chemical TN=Trade Name*	***INDICATION DESIGNATED***	***SPONSOR & ADDRESS*** *DD=Date Designated MA=Marketing Approval*
PURIFIED TYPE II COLLAGEN TN= COLLORAL	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	AUTOIMMUNE, INCORPORATED 128 SPRING STREET LEXINGTON MA 02173 DD 02/09/95 MA / /
RECOMBINANT HUMAN GELSOLIN TN=	TREATMENT OF ACUTE AND CHRONIC RESPIRATORY SYMPTOMS OF BRONCHIECTASIS.	BIOGEN, INCORPORATED 14 CAMBRIDGE CENTER CAMBRIDGE MA 02142 DD 03/06/95 MA / /
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 / /

Approved Orphan Products

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 APRIL 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 APRIL 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
D-27	BID DOSING IN PATIENTS 12 YEARS OF AGE AND OLDER FOR PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH MODERATELY EMETOGENIC CANCER CHEMOTHERAPY

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
I-122	PSORIASIS OF THE SCALP

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
20364 002	AMLODIPINE BESYLATE; LOTREL	4879303	NOV 07, 2006		NC	MAR 03, 1998
		4572909	AUG 01, 2006		NCE	JUN 25, 1996
		4410520	OCT 18, 2002		NCE	JUL 31, 1997
20364 003	AMLODIPINE BESYLATE; LOTREL	4879303	NOV 07, 2006		NC	MAR 03, 1998
		4572909	AUG 01, 2006		NCE	JUN 25, 1996
		4410520	OCT 18, 2002		NCE	JUL 31, 1997
20364 004	AMLODIPINE BESYLATE; LOTREL	4879303	NOV 07, 2006		NC	MAR 03, 1998
		4572909	AUG 01, 2006		NCE	JUN 25, 1996
		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
20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR				I-120	OCT 15, 1995
20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR				I-120	OCT 15, 1995
20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR				I-120	OCT 15, 1995
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		
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
20164 001	ENOXAPARIN SODIUM; LOVENOX				I-118	MAR 09, 1998
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			

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 004	ESTRADIOL; VIVELLE	5300291	APR 05, 2011			
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
			4814168	MAR 21, 2006			
	20375 001	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010		D-26	DEC 22, 1997
	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>	20325 001	FAMOTIDINE; PEPCID AC				NS	APR 28, 1998
>ADD>	19452 001	FLUOCINOLONE ACETONIDE; DERMA-SMOOTHE/FS				I-122	FEB 16, 1998
	20121 001	FLUTICASONE PROPIONATE; FLONASE	4335121	MAR 15, 2002		NCE	DEC 14, 1995
						NDF	OCT 19, 1997
	19915 004	FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000			
			4337201	JUN 29, 2001		NCE	MAY 16, 1996
	20460 001	GANCICLOVIR; CYTOVENE	4507305	OCT 19, 1999	U-64	NDF	DEC 22, 1997
>ADD>			4355032	MAR 16, 2003	U-64		
	20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 12, 2006	U-105	NCE	DEC 29, 1998
						NDF	MAR 16, 1998
>ADD>	20387 001	HYDROCHLOROTHIAZIDE; HYZAAR				NCE	APR 14, 2000
>ADD>						NC	APR 28, 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			
	20225 003	ISOSORBIDE MONONITRATE; IMDUR				NDF	AUG 12, 1996
						NCE	DEC 30, 1996
	19816 002	KETOPROFEN; ORUVAIL				NDF	SEP 24, 1996
	19816 003	KETOPROFEN; ORUVAIL				NDF	SEP 24, 1996
	20241 001	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
	20241 002	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
	20241 003	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
	20241 004	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
	20241 005	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
	20241 006	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
	20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		I-119	MAR 30, 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
	19670 001	LORATADINE; CLARITIN-D	4282233	AUG 04, 2000		NCE	APR 12, 1998
>ADD>	20386 001	LOSARTAN POTASSIUM; COZAAR				NCE	APR 14, 2000
>ADD>	20386 002	LOSARTAN POTASSIUM; COZAAR				NCE	APR 14, 2000
	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>	20312 001	MOEXIPRIL HYDROCHLORIDE; UNIVASC				NCE	APR 19, 2000
>ADD>	20312 002	MOEXIPRIL HYDROCHLORIDE; UNIVASC				NCE	APR 19, 2000
>ADD>	20459 001	NALMEFENE HYDROCHLORIDE; REVEX				NCE	APR 17, 2000
>ADD>	20459 002	NALMEFENE HYDROCHLORIDE; REVEX				NCE	APR 17, 2000
	20198 001	NIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010			
	20198 002	NIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010			
	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
>ADD>	20145 001	NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010			
>ADD>	20145 002	NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010			
>ADD>	20145 003	NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010			
>ADD>	20145 004	NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010			
>ADD>	20145 005	NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010			
>ADD>	20145 006	NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010			
	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
>ADD>						D-27	APR 10, 1998
>ADD>						I-9	APR 19, 1998
	20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		NCE	JAN 04, 1996
>ADD>						D-27	APR 10, 1998
>ADD>						I-9	APR 19, 1998
	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		

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
	18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150				I-120	MAR 29, 1998
	18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300				I-120	MAR 29, 1998
	19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	APR 29, 2003		I-120	MAR 29, 1998
	20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5028432	JUL 02, 2008		I-120	MAR 29, 1998
	20095 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5028432	JUL 02, 2008		I-120	MAR 29, 1998
	20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009		I-120	MAR 29, 1998
	20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009		I-120	MAR 29, 1998
	20236 001	SALMETEROL XINAFOATE; SEREVENT	5380922	JAN 10, 2012			
	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	5412095	MAR 15, 2011			
			5294615	MAR 15, 2011			
>ADD>			5212176	MAY 18, 2010			
>ADD>	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
			5294615	MAR 15, 2011			
>ADD>			5212176	MAY 18, 2010			
>ADD>	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
			5294615	MAR 15, 2011			
>ADD>			5212176	MAY 18, 2010			
>ADD>	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
			5294615	MAR 15, 2011			
>ADD>			5212176	MAY 18, 2010			
>ADD>	20347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
>ADD>	20347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
>ADD>	20347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
>ADD>	20347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
>ADD>	20439 001	TIMOLOL; BETIMOL	5231095	JUL 27, 2010		NP	MAR 31, 1998
>ADD>	20439 002	TIMOLOL; BETIMOL	5231095	JUL 27, 2010		NP	MAR 31, 1998
	20281 001	TRAMADOL HYDROCHLORIDE; ULTRAM				NCE	MAR 03, 2000
	20281 002	TRAMADOL HYDROCHLORIDE; ULTRAM				NCE	MAR 03, 2000
	20388 001	VINORELBINE TARTRATE; NAVELBINE	4307100	DEC 22, 1998		NCE	DEC 23, 1999

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