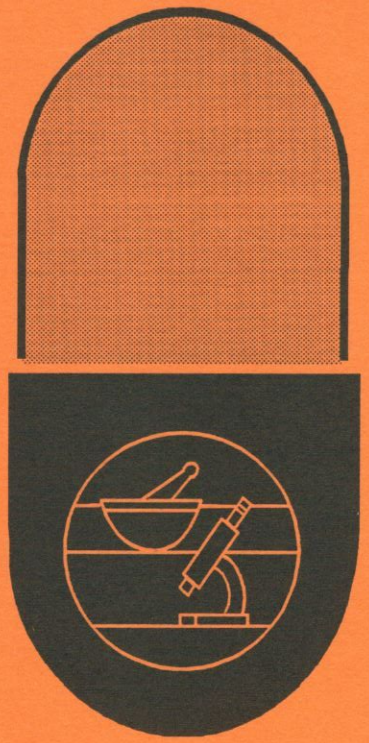
CUMULATIVE SUPPLEMENT 2

JAN'94-FEB'94



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION

Cumulative Supplement 2

FEBRUARY 1994

CONTENTS

THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION

CUMULATIVE SUPPLEMENT 2

FEBRUARY 1994

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, 14th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the " ∂ " symbol to designate their non-marketed status. All products having a " ∂ " symbol in the 12th Cumulative Supplement of the 14th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 15th 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; or when an applicant name is changed to meet internal publication standards. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
BANNER GELATIN PRODUCTS CORP (BANNER GELATIN)	BANNER PHARMACAPS INC (BANNER PHARMACAPS)
PHARMACAPS INC (PHARMACAPS)	BANNER PHARMACAPS INC (BANNER PHARMACAPS)
RICHLYN LABORATORIES INC (RICHLYN)	GLOBAL PHARMACEUTICAL CORPORATION (GLOBAL PHARM)

1.4 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

The U.S. Pharmacopeia (USP) periodically makes additions to or changes in monograph titles. Some of these additions or changes may affect dosage form terms listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (ADP). Instead of making the change in each affected product, the Cumulative Supplement (CS) will list applicable monograph title and dosage form additions or changes in this section. These will appear as soon as the modified USP monograph title is official. It is possible for these additions or changes to be listed in this section before all applicant holders have made labeling modifications.

The monograph title additions or changes shown below will remain in this section in each succeeding supplement of this edition. Once the next edition of the ADP is published, the products affected by the title additions or changes will be displayed with the new dosage form in the appropriate drug list. As notification to the reader, these monograph title additions or changes will also be listed in a special section of the ADP.

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

FORMER USP MONOGRAPH TITLE (FORMER ADP DOSAGE FORM; ROUTE)	NEW USP MONOGRAPH TITLE (NEW ADP DOSAGE FORM; ROUTE)

THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF FEBRUARY 1994.

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 1993) 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 1993	MAR 1994	JUN 1994	SEP 1994
DRUG PRODUCTS LISTED	9140			
SINGLE SOURCE	2144 (23.5%)			
MULTISOURCE	6996 (76.5%)			
THERAPEUTICALLY EQUIVALENT	6292 (68.8%)			
NOT THERAPEUTICALLY EQUIVALENT	527 (5.8%)			
EXCEPTIONS[1]	177 (1.9%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	526			

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

ACETIC ACID, GLACIAL; ALUMINUM ACETATE

SOLUTION/DROPS; OTIC

ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE

>ADD >					
>ADD >	AT	BAUSCH AND LOMB	2%;0.79%	N40063 001	
>ADD >				FEB 25, 1994	

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM

	AB	MYLAN	0.25MG	N74215 001	
				JAN 27, 1994	
	AB		0.5MG	N74215 002	
				JAN 27, 1994	
	AB		1MG	N74215 003	
				JAN 27, 1994	
	AB		2MG	N74215 004	
				JAN 27, 1994	
>ADD >	AB	NOVOPHARM	0.25MG	N74085 001	
>ADD >				FEB 16, 1994	
>ADD >	AB		0.5MG	N74085 002	
>ADD >				FEB 16, 1994	
>ADD >	AB		1MG	N74085 003	
>ADD >				FEB 16, 1994	

AMIKACIN SULFATE

INJECTABLE; INJECTION

AMIKACIN

>DLT >/AP/		/ELKINS/SINN/	/EQ 50MG BASE/ML/	/N63274/001/	
>DLT >				/MAY/18,/1992/	
>ADD >	AP	+ ELKINS SINN	EQ 50MG BASE/ML	N63274 001	
>ADD >				MAY 18, 1992	
>DLT >/AP/			/EQ 250MG BASE/ML/	/N63275/001/	
>DLT >				/MAY/18,/1992/	
>ADD >	AP	+	EQ 250MG BASE/ML	N63275 001	
>ADD >				MAY 18, 1992	
>DLT >		/AMIKIN/			
>DLT >/AP//+//BRISTOL/			/EQ 50MG BASE/ML/	/N50495/001/	
>DLT >/AP/			/EQ 50MG BASE/ML/	/N62562/001/	
>DLT >				/SEP/20,/1984/	
>DLT >/AP//+/			/EQ 250MG BASE/ML/	/N50495/002/	
>DLT >/AP/			/EQ 250MG BASE/ML/	/N62562/002/	
>DLT >				/SEP/20,/1984/	
>ADD >		ə APOTHECON	EQ 50MG BASE/ML	N50495 001	
>ADD >		ə	EQ 250MG BASE/ML	N50495 002	
>ADD >		ə BRISTOL	EQ 50MG BASE/ML	N62562 001	
>ADD >				SEP 20, 1984	
>ADD >		ə	EQ 250MG BASE/ML	N62562 002	
>ADD >				SEP 20, 1984	

AMINOPHYLLINE

TABLET; ORAL

AMINOPHYLLINE

>ADD >	AB	RICHLYN	100MG	N84574 001	
>ADD >	AB		200MG	N84576 001	
>DLT > /BD/			/100MG/	/N84574/001/	
>DLT > /BD/			/200MG/	/N84576/001/	

ATENOLOL

TABLET; ORAL

ATENOLOL

>ADD >	AB	INVAMED	25MG	N74265 001	
>ADD >				FEB 28, 1994	
>ADD >	AB		50MG	N74265 002	
>ADD >				FEB 28, 1994	
>ADD >	AB		100MG	N74265 003	
>ADD >				FEB 28, 1994	

BACITRACIN

OINTMENT; OPHTHALMIC

BACITRACIN

>DLT >/AT/		/PHARMAFAIR/	/500 UNITS/GM/	/N62453/001/	
>DLT >				/MAR/28,/1984/	
>ADD >		ə PHARMAFAIR	500 UNITS/GM	N62453 001	
>ADD >				MAR 28, 1984	

BACLOFEN

TABLET; ORAL

BACLOFEN

	AB	ROYCE	10MG	N73092 001	
				JAN 28, 1994	
	AB		20MG	N73093 001	
				JAN 28, 1994	

BUDESONIDE

AEROSOL, METERED; NASAL

RHINOCORT

>ADD >		+ ASTRA	0.05MG/INH	N20233 001	
>ADD >				FEB 14, 1994	

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

	/CEFADROXIL/			
/AB/	/ZENITH/	/EQ 500MG BASE/	/N62766/001/	
			/MAR/03,/1987/	
	ə ZENITH	EQ 500MG BASE	N62766 001	
			MAR 03, 1987	

TABLET; ORAL

	/CEFADROXIL/			
/AB/	/ZENITH/	/EQ 1GM BASE/	/N62774/001/	
			/APR/08,/1987/	
	ə ZENITH	EQ 1GM BASE	N62774 001	
			APR 08, 1987	

CHLORAMPHENICOL

OINTMENT; OPHTHALMIC

>DLT>	/CHLOROFAIR/			
>DLT>/AT/	/PHARMAFAIR/	/1%/	/N62439/001/	
>DLT>			/APR/21,/1983/	
>ADD>	ə PHARMAFAIR	1%	N62439 001	
>ADD>			APR 21, 1983	

SOLUTION/DROPS; OPHTHALMIC

>DLT>	/CHLOROFAIR/			
>DLT>/AT/	/PHARMAFAIR/	/0.5%/	/N62437/001/	
>DLT>			/APR/14,/1983/	
>ADD>	ə PHARMAFAIR	0.5%	N62437 001	
>ADD>			APR 14, 1983	

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

	PERIDEX		
AT	+ P AND G	0.12%	N19028 001
			AUG 13, 1986
	PERIOGARD		
AT	COLGATE PALMOLIVE	0.12%	N73695 001
			JAN 14, 1994

CHLORTHALIDONE

TABLET; ORAL

	THALITONE		
	+ HORUS THERAP	15MG	N19574 001
			DEC 20, 1988
		/15MG/	/N19574/001/
			/DEC/20,/1988/

CLOBETASOL PROPIONATE

CREAM; TOPICAL

>ADD>		CLOBETASOL PROPIONATE		
>ADD> AB		COPLEY	0.05%	N74087 001
>ADD>				FEB 16, 1994
		TEMOVATE		
>ADD> AB	+	GLAXO	0.05%	N19322 001
>ADD>				DEC 27, 1985

OINTMENT; TOPICAL

>ADD>		CLOBETASOL PROPIONATE		
>ADD> AB		COPLEY	0.05%	N74089 001
>ADD>				FEB 16, 1994
		TEMOVATE		
>ADD> AB	+	GLAXO	0.05%	N19323 001
>ADD>				DEC 27, 1985

CORTISONE ACETATE

INJECTABLE; INJECTION

		CORTISONE ACETATE		
>DLT> /BP/		/STERIS/	/25MG/ML/	/N83147/003/
>DLT> /BP/			/50MG/ML/	/N83147/004/
>ADD>	ə	STERIS	25MG/ML	N83147 003
>ADD>	ə		50MG/ML	N83147 004
>DLT> /BP/		/UPJOHN/	/25MG/ML/	/N08126/002/
>ADD>	ə	UPJOHN	25MG/ML	N08126 002

CYTARABINE

INJECTABLE; INJECTION

		CYTARABINE		
>ADD>	+	BULL	20MG/ML	N72945 001
>ADD>				FEB 28, 1994

DEXTROAMPHETAMINE SULFATE

>DLT>	/ELIXIR;ORAL/			
>DLT>	/DEXEDRINE/			
>DLT>	/SMITHKLINE/BEECHAM/		/5MG/5ML/	/N83902/001/
>ADD>	ə SMITHKLINE BEECHAM		5MG/5ML	N83902 001

DEXTROTHYROXINE SODIUM

TABLET; ORAL
CHOLOXIN

> ADD >		+ BOOTS	4MG	N12302 004
> DLT >		/*/	/6MG/	/N12302/006/
> DLT >			/4MG/	/N12302/004/
> ADD >		ə	6MG	N12302 006

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

> ADD >	AB	NOVOPHARM	30MG	N74084 001
> ADD >				FEB 25, 1994
> ADD >	AB		60MG	N74084 002
> ADD >				FEB 25, 1994

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN

	AT	BAUSCH AND LOMB	2%	N64039 001
				JAN 27, 1994

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL
ERYTHROMYCIN ETHYLSUCCINATE

> DLT >	AB	/DISTA/	/EQ 200MG BASE/5ML/	/N62177/001/
> DLT >	AB		/EQ 400MG BASE/5ML/	/N62177/002/
> ADD >		ə DISTA	EQ 200MG BASE/5ML	N62177 001
> ADD >		ə	EQ 400MG BASE/5ML	N62177 002

TABLET; ORAL
E.E.S. 400

> DLT >	AB	/*//ABBOTT/	/EQ 400MG BASE/	/N61905/001/
> DLT >	AB		/EQ 400MG BASE/	/N61905/002/
> DLT >				/AUG/12,/1982/
> ADD >	AB	+ ABBOTT	EQ 400MG BASE	N61905 002
> ADD >				AUG 12, 1982
> ADD >		ə	EQ 400MG BASE	N61905 001

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

> DLT >		/DELADUMONE/		
> DLT >	AO	/*//SQUIBB/	/4MG/ML;20MG/ML/	/N09545/001/

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

> DLT >		/DELADUMONE/		
> ADD >		ə SQUIBB	4MG/ML;90MG/ML	N09545 001

TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE

> DLT >	AO	/STERIS/	/4MG/ML;90MG/ML/	/N85865/001/
> ADD >		+ STERIS	4MG/ML;90MG/ML	N85865 001

ETOPOSIDE

INJECTABLE; INJECTION
ETOPOSIDE

> ADD >	AP	GENSIA	20MG/ML	N74284 001
> ADD >				FEB 10, 1994

VEPESID

> ADD >	AP	+ BRISTOL	20MG/ML	N18768 001
> ADD >				NOV 10, 1983

FAMOTIDINE

INJECTABLE; INJECTION
PEPCID IN PLASTIC CONTAINER

> ADD >		+ MERCK	0.4MG/ML	N20249 001
> ADD >				FEB 18, 1994

FLUMAZENIL

INJECTABLE; INJECTION

> DLT >		/MAZICON/		
> DLT >		/*//ROCHE/	/0.1MG/ML/	/N20073/001/
> DLT >				/DEC/20,/1991/
> ADD >		ROMAZICON		
> ADD >		+ ROCHE	0.1MG/ML	N20073 001
> ADD >				DEC 20, 1991

FOLIC ACID

TABLET; ORAL
FOLIC ACID

> DLT >	AA	/PUREPAC/	/1MG/	/N80784/001/
> ADD >		ə PUREPAC	1MG	N80784 001

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION
GALLIUM CITRATE GA 67

>ADD >	BS	DUPONT	2MCI/ML		N17478 001
>DLT >	/BS/	/DUPONT/MERCK/	/2MCI/ML/		/N17478/001/

GUANABENZ ACETATE

TABLET; ORAL
GUANABENZ ACETATE

>ADD >					
>ADD >	AB	WATSON LABS	EQ 4MG BASE		N74025 001
>ADD >					FEB 28, 1994
>ADD >	AB		EQ 8MG BASE		N74025 002
>ADD >					FEB 28, 1994

WYTENSIN

>ADD >	AB	WYETH AYERST	EQ 4MG BASE		N18587 001
>ADD >					SEP 07, 1982
>ADD >	AB +		EQ 8MG BASE		N18587 002
>ADD >					SEP 07, 1982

HEPARIN CALCIUM

INJECTABLE; INJECTION
CALCIPARINE

>ADD >		+ CHOAY	25,000 UNITS/ML		N18237 001
>DLT >		/+//DUPONT/	/25,000/UNITS/ML/		/N18237/001/

HYDROCORTISONE

LOTION; TOPICAL
HYDROCORTISONE

>DLT >/AT/		/CLAY/PARK/	/1%/		/N85663/001/
>ADD >		@ CLAY PARK	1%		N85663 001

OINTMENT; TOPICAL
HYDROCORTISONE

>DLT >/AT/		/CLAY/PARK/	/1%/		/N85028/001/
>ADD >		@ CLAY PARK	1%		N85028 001

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
>DLT > /DELALUTIN/

>DLT >/AO/		/77777777/	/125MG/ML/		/N16347/004/
>DLT >/AO/			/125MG/ML/		/N16911/001/
>DLT >/AO/	+/		/250MG/ML/		/N16347/002/
>DLT >/AO/			/250MG/ML/		/N16911/002/

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
>DLT > /DELALUTIN/

>ADD >		@ SQUIBB	125MG/ML		N10347 004
>ADD >		@	125MG/ML		N16911 001
>ADD >		@	250MG/ML		N10347 002
>ADD >		@	250MG/ML		N16911 002

HYDROXYPROGESTERONE CAPROATE

>DLT >/AO/		/STERIS/	/125MG/ML/		/N17439/001/
>ADD >	AO +	STERIS	125MG/ML		N17439 001
>DLT >/AO/			/250MG/ML/		/N17439/002/
>ADD >		+	250MG/ML		N17439 002

IODOHIPPURATE SODIUM, I-123

>DLT >		/INJECTABLE;/INJECTION/			
>DLT >		/NEPHROFLOW/			
>DLT >		/MEDI/PHYSICS/	/1MCI/ML/		/N18289/001/
>DLT >					/DEC/28,/1984/
>ADD >		@ MEDI PHYSICS	1MCI/ML		N18289 001
>ADD >					DEC 28, 1984

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX

>DLT >/AB/		/APOTHECON/	/EQ 500MG BASE/		/N62726/001/
>DLT >					/MAR/06,/1987/
>ADD >		+ APOTHECON	EQ 500MG BASE		N61911 001
>ADD >		@	EQ 500MG BASE		N60516 001
>ADD >			EQ 500MG BASE		N62726 001
>ADD >					MAR 06, 1987
>DLT >/AB/	/+/	/BRISTOL/	/EQ 500MG BASE/		/N60516/001/
>DLT >/AB/			/EQ 500MG BASE/		/N61911/001/

INJECTABLE; INJECTION
KANTREX

>ADD >	AP	+ APOTHECON	EQ 75MG BASE/2ML		N61655 003
>ADD >	AP	+	EQ 500MG BASE/2ML		N61655 001
>ADD >	AP	+	EQ 1GM BASE/3ML		N61655 002
>ADD >		@	EQ 75MG BASE/2ML		N62564 001
>ADD >					SEP 21, 1984
>ADD >		@	EQ 500MG BASE/2ML		N62564 002
>ADD >					SEP 21, 1984
>ADD >		@	EQ 1GM BASE/3ML		N62564 003
>ADD >					SEP 21, 1984

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANTREX

>DLT>	/AP//+//BRISTOL/	/EQ 75MG BASE/2ML/	/N61655/003/		
>DLT>	/AP/	/EQ 75MG BASE/2ML/	/N62564/001/		
>DLT>			/SEP/21,/1984/		
>DLT>	/AP//+/	/EQ 500MG BASE/2ML/	/N61655/001/		
>DLT>	/AP/	/EQ 500MG BASE/2ML/	/N62564/002/		
>DLT>			/SEP/21,/1984/		
>DLT>	/AP//+/	/EQ 1GM BASE/3ML/	/N61655/002/		
>DLT>	/AP/	/EQ 1GM BASE/3ML/	/N62564/003/		
>DLT>			/SEP/21,/1984/		

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM

>DLT>	/+//IMMUNEX/	/EQ/3MG/BASE/ML/	/N08107/001/		
>ADD>	@ IMMUNEX	EQ 3MG BASE/ML	N08107 001		

METHAZOLAMIDE

TABLET; ORAL

METHAZOLAMIDE

AB	MIKART	25MG	N40062 001		
			JAN 27, 1994		
AB		50MG	N40062 002		
			JAN 27, 1994		

METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE

AB	APOTHECON	50MG	N74258 001		
			JAN 27, 1994		
AB		100MG	N74258 002		
			JAN 27, 1994		
AB	COPLEY	50MG	N74333 001		
			JAN 27, 1994		
AB		100MG	N74333 002		
			JAN 27, 1994		

NAFCILLIN SODIUM

INJECTABLE; INJECTION

UNIPEN

>ADD> AP	WYETH AYERST	EQ 10GM BASE/VIAL	N50320 005		
>ADD>	@	EQ 20GM BASE/VIAL	N50320 006		

NAPROXEN

TABLET; ORAL

NAPROXEN

>ADD> AB	ROXANE	250MG	N74211 001		
>ADD>			FEB 28, 1994		
>ADD> AB		375MG	N74211 002		
>ADD>			FEB 28, 1994		
>ADD> AB		500MG	N74211 003		
>ADD>			FEB 28, 1994		

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

AB	COPLEY	EQ 250MG BASE	N74289 001		
			JAN 27, 1994		
AB		EQ 500MG BASE	N74289 002		
			JAN 27, 1994		

NITROGLYCERIN

INJECTABLE; INJECTION

>DLT>	/NITRONAL/				
>DLT>	/+//BOSKAMP/	/1MG/ML/	/N18672/001/		
>DLT>			/AUG/30,/1983/		
>ADD>	@ G POHL BOSKAMP	1MG/ML	N18672 001		
>ADD>			AUG 30, 1983		

NORETHINDRONE

TABLET; ORAL

>DLT>	/NORLUTIN/				
>DLT>	/+//PARKE/DAVIS/	/5MG/	/N10895/002/		
>ADD>	@ PARKE DAVIS	5MG	N10895 002		

NYSTATIN

SUSPENSION; ORAL

NYSTATIN

>ADD> AA	BAUSCH AND LOMB	100,000 UNITS/ML	N64042 001		
>ADD>			FEB 28, 1994		

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

>DLT >/AT/	/PHARMAFAIR/	/100,000 UNITS/GM;0.1%/	/N62657/001/	
>DLT >			/JUL/30,/1986/	
>ADD >	@ PHARMAFAIR	100,000 UNITS/GM;0.1%	N62657 001	
>ADD >			JUL 30, 1986	

ORPHENADRINE HYDROCHLORIDE

TABLET; ORAL
DISPAL

>DLT >	/3M/	/50MG/	/N10653/001/	
>ADD >	@ 3M	50MG	N10653 001	

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM

>ADD >	@ APOTHECON	1,000,000 UNITS/VIAL	N60362 001	
>ADD >	@	5,000,000 UNITS/VIAL	N60362 003	
>ADD >	@	10,000,000 UNITS/VIAL	N60362 004	
>ADD >	@	20,000,000 UNITS/VIAL	N60362 002	
>DLT >/AP/	/SQUIBB/	/1,000,000 UNITS/VIAL/	/N60362/001/	
>DLT >/AP/		/5,000,000 UNITS/VIAL/	/N60362/003/	
>DLT >/AP/		/10,000,000 UNITS/VIAL/	/N60362/004/	
>DLT >/AP/		/20,000,000 UNITS/VIAL/	/N60362/002/	

PINDOLOL

TABLET; ORAL
PINDOLOL

AB	MUTUAL PHARM	5MG	N74063 001	
			JAN 27, 1994	
AB		10MG	N74063 002	
			JAN 27, 1994	

PIROXICAM

CAPSULE; ORAL
PIROXICAM

AB	NOVOPHARM	10MG	N73637 001	
			JAN 28, 1994	
AB		20MG	N73638 001	
			JAN 28, 1994	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

>DLT >	/PREDAIR FORTE/			
>DLT >/AT/	/PHARMAFAIR/	/EQ 0.9% PHOSPHATE/	/N88165/001/	
>DLT >			/MAR/28,/1983/	
>ADD >	@ PHARMAFAIR	EQ 0.9% PHOSPHATE	N88165 001	
>ADD >			MAR 28, 1983	

PROPANTHELINE BROMIDE

TABLET; ORAL
PRO-BANTHINE

>ADD > AA	ROBERTS	7.5MG	N08732 003	
>ADD > AA		15MG	N08732 002	
>DLT >/AA/	/SCS/PHARMS/	/7.5MG/	/N08732/003/	
>DLT >/AA/		/15MG/	/N08732/002/	

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL
ALLERFED

>DLT >				
>DLT >/AA/	/PRIVATE FORM/	/60MG;2.5MG/	/N88860/001/	
>DLT >			/JAN/31,/1985/	
>ADD >	@ PRIVATE FORM	60MG;2.5MG	N88860 001	
>ADD >			JAN 31, 1985	

>ADD > SALMETEROL XINAFOATE

AEROSOL, METERED; INHALATION
SEREVENT

>ADD >	+ GLAXO	EQ 0.021MG BASE/INH	N20236 001	
>ADD >			FEB 04, 1994	

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULFAIR FORTE

>DLT >				
>DLT >/AT/	/PHARMAFAIR/	/30%/	/N88385/001/	
>DLT >			/OCT/13,/1983/	
>ADD >	@ PHARMAFAIR	30%	N88385 001	
>ADD >			OCT 13, 1983	

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION
CARDIOLITE

>_ADD_>		DUPONT	N/A	N19785 001	
>_ADD_>				DEC 21, 1990	
>_DLT_>		/DUPONT/MERCK/	/N/A/	/N19785/001/	
>_DLT_>				/DEC/21,/1990/	

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
SLO-BID

>_ADD_>	AB	RHONE POULENC RORER	100MG	N87892 001	
>_ADD_>				JAN 31, 1985	
>_ADD_>	AB		125MG	N89540 001	
>_ADD_>				MAY 10, 1989	
>_ADD_>	AB		200MG	N87893 001	
>_ADD_>				JAN 31, 1985	
>_ADD_>	AB	+	300MG	N87894 001	
>_ADD_>				JAN 31, 1985	

THEOPHYLLINE

>_ADD_>	AB	INWOOD LABS	100MG	N40052 001	
>_ADD_>				FEB 14, 1994	
>_ADD_>	AB		125MG	N40052 002	
>_ADD_>				FEB 14, 1994	
>_ADD_>	AB		200MG	N40052 003	
>_ADD_>				FEB 14, 1993	
>_ADD_>	AB		300MG	N40052 004	
>_ADD_>				FEB 14, 1994	

ELIXIR; ORAL
THEOPHYLLINE

>_ADD_>		∂ CENCI	80MG/15ML	N87679 001	
>_ADD_>				APR 15, 1982	
>_DLT_>	/AA/	/LIFE/LABS/	/80MG/15ML/	/N87679/001/	
>_DLT_>				/APR/15,/1982/	

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
ISOPTIN SR

	AB	+ KNOLL	180MG	N19152 002	
				DEC 15, 1989	

VERAPAMIL HCL

	AB	BAKER NORTON	180MG	N74330 001	
				JAN 31, 1994	

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

>_DLT_>	/AP/	/BULL/	/10MG/VIAL/	/N89565/001/	
>_DLT_>				/AUG/18,/1987/	
>_ADD_>	AP	FAULDING	10MG/VIAL	N89565 001	
>_ADD_>				AUG 18, 1987	

VINCRISTINE SULFATE

INJECTABLE; INJECTION
VINCRISTINE SULFATE PFS

>_DLT_>	/AP/	/BULL/	/1MG/ML/	/N71484/001/	
>_DLT_>				/APR/19,/1988/	
>_ADD_>	AP	FAULDING	1MG/ML	N71484 001	
>_ADD_>				APR 19, 1988	

IBUPROFEN

TABLET; ORAL
IBUPROFEN

>ADD<	PRIVATE FORM	200MG	N73691 001
>ADD<			FEB 25, 1994

NAPROXEN SODIUM

TABLET; ORAL
ALEVE

HAMILTON PHARMS	EQ 200MG BASE	N20204 002
		JAN 11, 1994

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 2 / FEB '94

NO FEBRUARY 1994 APPROVALS

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS

[January-February, 1994]

NAME *Generic/Chemical* *TN=Trade Name*	***INDICATION DESIGNATED***	***SPONSOR & ADDRESS*** *DD=Date Designated* *MA=Marketing Approval*
AMMONIUM TETRATHIOMOLYBDATE TN=	TREATMENT OF WILSON'S DISEASE.	BREWER, GEORGE J. M.D. UNIVERSITY OF MICHIGAN MEDICAL SCHOOL ANN ARBOR MI 48109-0618 DD 01/31/94 MA / /
ANTIVENIN, POLYVALENT CROTALID (OVINE) FAB TN= CROTAB	TREATMENT OF ENVENOMATIONS INFLICTED BY NORTH AMERICAN CROTALID SNAKES.	THERAPEUTIC ANTIBODIES INC. 1500 21ST AVENUE SOUTH, SUITE 310 NASHVILLE TN 37212 DD 01/12/94 MA / /
CHOLINE CHLORIDE TN=	TREATMENT OF CHOLINE DEFICIENCY,SPECIFICALLY THE CHOLINE DEFICIENCY, HEPATIC STEATOSIS, AND CHOLESTASIS, ASSOCIATED WITH LONG-TERM PARENTERAL NUTRITION.	BUCHMAN, ALAN M.D. 6550 FANNIN, SUITE 1122 HOUSTON TX 77030 DD 02/10/94 MA / /
FGN-1 TN=	FOR THE SUPPRESSION AND CONTROL OF COLONIC ADENOMATOUS POLYPS IN THE INHERITED DISEASE ADENOMATOUS POLYPOSIS COLI.	CELL PATHWAYS, INC. 1700 BROADWAY, SUITE 2000 DENVER CO 80290 DD 02/14/94 MA / /
RECOMBINANT HUMAN GELSOLIN TN=	TREATMENT OF THE RESPIRATORY SYMPTOMS OF CYSTIC FIBROSIS.	BIOGEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02124 DD 01/12/94 MA / /
REDUCED L-GLUTATHIONE TN= CACHEXON	TREATMENT OF AIDS-ASSOCIATED CACHEXIA.	TELLURIDE PHARMACEUTICAL CORPORATION 146 FLANDERS DRIVE HILLSBOROUGH NJ 08876-4656 DD 02/14/94 MA / /
TIZANIDINE HCL TN= ZANAFLEX	TREATMENT OF SPASTICITY ASSOCIATED WITH MULTIPLE SCLEROSIS AND SPINAL CORD INJURY.	ATHENA NEUROSCIENCES, INC. 800F GATEWAY BOULEVARD SOUTH SAN FRANCISCO CA 94080 DD 01/31/94 MA / /

ORPHAN DRUG APPROVALS

PEGASPARGASE TN= ONCASPAR	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA (ALL).	ENZON, INC. 40 KINGSBRIDGE ROAD PISCATAWAY NJ 08854-3998 DD 10/20/89 MA 02/01/94

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

NO FEBRUARY 1994 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, 13TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ALBUTEROL (METERED DOSE INHALER - *IN VIVO*)	JAN 27, 1994	

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 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ACYCLOVIR TABLET; ORAL	200MG	93 P-0339/ CP1	NOVOPHARM	NEW DOSAGE FORM	APPROVED FEB 08, 1994
LOPERAMIDE HYDROCHLORIDE TABLET, EFFERVESCENT; ORAL	1MG	93 P-0332/ CP1	ELLIS PHARM CONSULTING	NEW DOSAGE FORM	APPROVED FEB 08, 1994
PSEUDOEPHEDRINE HYDROCHLORIDE; TERFENADINE CAPSULE, EXTENDED RELEASE; ORAL	120MG 60MG	93 P-0367/ CP1	EURAND AMERICA	NEW DOSAGE FORM	APPROVED FEB 08, 1994

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, 14TH 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-21 ALTERNATIVE DOSAGE OF 300MG ONCE DAILY AFTER THE EVENING MEAL

REFERENCES
NEW INDICATION

I-99 PEDIATRIC ANESTHESIA IN CHILDREN 3 YEARS AND OLDER
I-100 TO DECREASE THE INCIDENCE OF CANDIDIASIS IN PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION WHO RECEIVE CYTOTOXIC CHEMOTHERAPY AND/OR RADIATION THERAPY
I-101 TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN-DEPENDENT DIABETES MELLITUS AND RETINOPATHY
I-102 TREATMENT OF OBSESSIVE-COMPULSIVE DISORDER
I-103 PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOCOMPROMISED AND CONSIDERED TO BE AT RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA

REFERENCES
PATENT USE CODE

U-91 ALTERNATIVE THERAPY TO TRIMETHOPRIM-SULFAMETHOXAZOLE FOR TREATMENT OF MODERATE-TO-SEVERE PNEUMOCYSTIS CARINII PNEUMONIA IN IMMUNOCOMPROMISED AND AIDS PATIENTS

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>	18700 001	AMRINONE LACTATE; INOCOR	4072746	JUL 31, 1998	U-7	NCE	JUL 31, 1994
>DLT>	~~18700 001~~	~~AMRINONE LACTATE; INOCOR~~	~~4072746~~	~~APR 23, 1998~~	~~U-7~~	~~NCE~~	~~JUL 31, 1994~~
>ADD>	20304 001	APROTININ BOVINE; TRASYLOL				ODE	DEC 29, 2000
>ADD>	20233 001	BUDESONIDE; RHINOCORT				NCE	FEB 14, 1999
	18343 001	CAPTOPRIL; CAPOTEN				I-101	JAN 28, 1997
	18343 002	CAPTOPRIL; CAPOTEN				I-101	JAN 28, 1997
	18343 003	CAPTOPRIL; CAPOTEN				I-101	JAN 28, 1997
	18343 005	CAPTOPRIL; CAPOTEN				I-101	JAN 28, 1997
>ADD>	20249 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
	19304 001	FENOFIBRATE; LIPIDIL	4058552	NOV 15, 1994		NCE	DEC 31, 1998
	19949 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
	19949 002	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
	19949 003	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
	19950 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
>ADD>	18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4018895	APR 19, 1994	U-12	I-102	FEB 28, 1997
>ADD>	18936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-102	FEB 28, 1997
>ADD>	20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-102	FEB 28, 1997
>ADD>	19778 003	HYDROCHLOROTHIAZIDE; PRINZIDE 10-12.5	4472380	SEP 18, 2001			
>ADD>			4374829	DEC 30, 2001	U-3	NS	NOV 18, 1996
>ADD>	19888 001	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-12.5	4472380	SEP 18, 2001			
>ADD>			4374829	DEC 30, 2001	U-3		
>ADD>	19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-25	4374829	DEC 30, 2001	U-3		
>ADD>	19888 003	HYDROCHLOROTHIAZIDE; ZESTORETIC 10-12.5	4472380	SEP 18, 2001		NS	NOV 18, 1996
>ADD>			4374829	DEC 30, 2001	U-3		
	20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4369184	JAN 18, 2000		NCE	NOV 10, 1998
	20264 001	MEGESTROL ACETATE; MEGACE				NDF	SEP 10, 1997
>ADD>	20184 001	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
>ADD>	20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
>ADD>	20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
	20279 001	PREDNICARBATE; DERMATOP				NDF	OCT 29, 1996
	19627 001	PROPOFOL; DIPRIVAN				I-99	OCT 26, 1996
>ADD>	18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4128658	DEC 05, 1995		D-21	FEB 28, 1997
>ADD>	18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	4128658	DEC 05, 1995		D-21	FEB 28, 1997
>ADD>	19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4521431	JUN 04, 2002		D-21	FEB 28, 1997
>ADD>	20236 001	SALMETEROL XINAFOATE; SEREVENT	4992474	FEB 12, 2008		NCE	FEB 04, 1999
>ADD>	17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997		I-103	JAN 07, 1997
>ADD>	17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997		I-103	JAN 07, 1997

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	17377 001	SULFAMETHOXAZOLE; BACTRIM				I-103	JAN 07, 1997
>ADD>	17377 002	SULFAMETHOXAZOLE; BACTRIM DS				I-103	JAN 07, 1997
>ADD>	17598 001	SULFAMETHOXAZOLE; SEPTRA				I-103	JAN 07, 1997
>ADD>	17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE				I-103	JAN 07, 1997
>ADD>	17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC				I-103	JAN 07, 1997
	20284 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997			
	20284 002	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997			
>ADD>	20330 001	TIMOLOL MALEATE; TIMOPTIC-XE	4861760	AUG 29, 2006			
>ADD>			4195085	MAR 25, 1997		NP	NOV 04, 1996
>ADD>	20330 002	TIMOLOL MALEATE; TIMOPTIC-XE	4861760	AUG 29, 2006			
>ADD>			4195085	MAR 25, 1997		NP	NOV 04, 1996
>ADD>	20326 001	TRIMETREXATE GLUCURONATE; NEUTREXIN	4694007	SEP 15, 2004	U-91	ODE	DEC 17, 2000
>DLT>	~~20326 001~~	~~TRIMETREXATE GLUCURONATE; NEUTREXIN~~				~~ODE~~	~~DEC 17, 2000~~

*U.S. Government Printing Office: 1994 — 301-037/80009