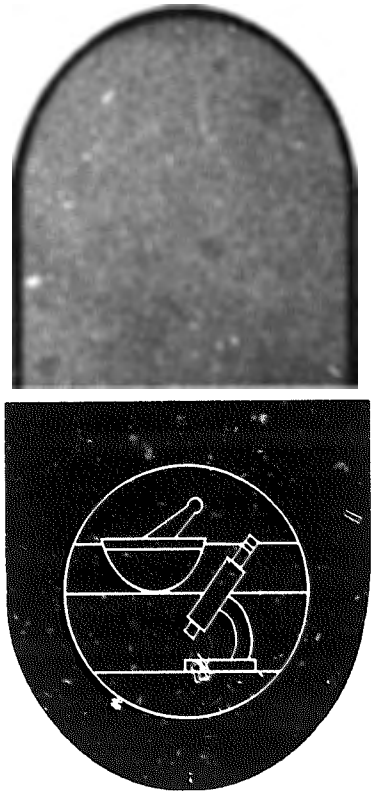
CUMULATIVE SUPPLEMENT 1

JAN'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 1

JANUARY 1995

CONTENTS

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15TH EDITION

CUMULATIVE SUPPLEMENT 1

JANUARY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)

THERE WERE NO APPLICANT NAME CHANGES IN JANUARY 1995.

1.4 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

The October 1994 through December 1994 quarterly subscription of the *Approved Drug Products with Therapeutic Equivalence Evaluations,* 14th Edition is now available on a 3 1/2" diskette. The diskette contains the Prescription Drug Product List, OTC Drug Product List and the Discontinued Drug Product List. The diskettes are available from the National Technical Information Service, 5285 Port Royal Road Springfield, VA 22161. The telephone number for the Subscription Department is (703) 487-6430.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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

DEFINITIONS

Drug Product

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

New Molecular Entity

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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

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

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

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PAGE

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

> DLT >	AB	ROXANE	150MG	N86090 001	
> ADD >		@	150MG	N86090 001	

ASPIRIN; METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL AND ASPIRIN

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

ATENOLOL

TABLET; ORAL
ATENOLOL

> ADD >	AB	LEMMON	50MG	N74056 001 JAN 18, 1995
> ADD >	AB		100MG	N74056 002 JAN 18, 1995

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
BACITRACIN ZINC AND POLYMYXIN B SULFATE

> ADD >	AT	ADV REMEDIES	500 UNITS/GM; 10,000 UNITS/GM	N64028 001 JAN 30, 1995
> ADD >	AT	BAUSCH AND LOMB	500 UNITS/GM; 10,000 UNITS/GM	N64046 001 JAN 26, 1995

POLYSPORIN

> ADD >	AT	+ BURROUGHS WELLCOME	500 UNITS/GM; 10,000 UNITS/GM	N61229 001

BUMETANIDE

INJECTABLE; INJECTION
BUMETANIDE

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

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

> DLT >	AB	LEMMON	100MG	N88768 001 OCT 11, 1984
> ADD >		@	100MG	N88768 001 OCT 11, 1984

GLUCAMIDE

> DLT >	AB	LEMMON	250MG	N88641 001 OCT 11, 1984
> ADD >		@	250MG	N88641 001 OCT 11, 1984

CHOLESTYRAMINE

TABLET; ORAL
QUESTRAN

> DLT >		+ BRISTOL MYERS SQUIBB	EQ 1GM RESIN	N73402 001 APR 28, 1994
> ADD >		@	EQ 1GM RESIN	N73403 001 APR 28, 1994

CIMETIDINE

TABLET; ORAL
CIMETIDINE

> ADD >	AB	GENEVA PHARMS	200MG	N74100 001 JAN 31, 1995
> ADD >	AB		300MG	N74100 002 JAN 31, 1995
> ADD >	AB		400MG	N74100 003 JAN 31, 1995
> ADD >	AB		800MG	N74100 004 JAN 31, 1995

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

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

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC

> ADD >		CROLOM			
> ADD >	AT	BAUSCH AND LOMB	4%	N74443 001	
> ADD >				JAN 30, 1995	
		OPTICROM			
> ADD >	AT +	FISONS	4%	N18155 001	
> ADD >				OCT 03, 1984	

CYANOCOBALAMIN

INJECTABLE; INJECTION

		RUBRAMIN PC			
> DLT >	AP +	SQUIBB	0.1MG/ML	N06799 002	
> ADD >		@	0.1MG/ML	N06799 002	

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

> DLT >		DESMOPRESSIN ACETATE			
> DLT >		+ RHONE POULENC RORER	0.15MG/INH	N20355 001	
> DLT >				MAR 07, 1994	
> ADD >		STIMATE			
> ADD >		+ RHONE POULENC RORER	0.15MG/INH	N20355 001	
> ADD >				MAR 07, 1994	

DICLOFENAC POTASSIUM

TABLET; ORAL

		CATAFLAM			
> DLT >		GEIGY	25MG	N20142 001	
> DLT >				NOV 24, 1993	
> ADD >		@	25MG	N20142 001	
> ADD >				NOV 24, 1993	

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

		VIVELLE			
> ADD >	BX	CIBA GEIGY	0.05MG/24HR	N20323 002	
> ADD >				OCT 28, 1994	
> ADD >	BX		0.1MG/24HR	N20323 004	
> ADD >				OCT 28, 1994	

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

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

FLURBIPROFEN SODIUM

SOLUTION/DROPS; OPHTHALMIC

> ADD >		FLURBIPROFEN SODIUM			
> ADD >	AT	BAUSCH AND LOMB	0.03%	N74447 001	
> ADD >				JAN 04, 1995	
		OCUFEN			
> ADD >	AT +	ALLERGAN	0.03%	N19404 001	
> ADD >				DEC 31, 1986	

GEMFIBROZIL

CAPSULE; ORAL

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

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

> DLT >		APRESOLINE-ESIDRIX			
> DLT >		+ CIBA	25MG;15MG	N12026 002	
> ADD >		@	25MG;15MG	N12026 002	

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

> DLT >	AP	PHARMAFAIR	50MG/ML	N88881 001	
> DLT >				FEB 14, 1986	
> ADD >		@	50MG/ML	N88881 001	
> ADD >				FEB 14, 1986	

IBUPROFEN

SUSPENSION; ORAL

CHILDREN'S MOTRIN

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

PEDIA PROFEN

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

LEUPROLIDE ACETATE

INJECTABLE; INJECTION

LUPRON

> DLT >		+ TAP PHARMS	5MG/ML	N19010 001	
> DLT >				APR 09, 1985	
> ADD >		+	1MG/0.2ML	N19010 001	
> ADD >				APR 09, 1985	

MEBENDAZOLE

TABLET, CHEWABLE; ORAL

MEBENDAZOLE

> ADD >					
> ADD >	AB	COPLEY PHARM	100MG	N73580 001	
> ADD >				JAN 04, 1995	

VERMOX

> ADD >	AB	+ JANSSEN	100MG	N17481 001	

METHADONE HYDROCHLORIDE

POWDER; FOR RX COMPOUNDING

METHADONE HCL

> ADD >				
> ADD >				
> ADD >	MALLINCKRODT	50GM/BOT	N06383 002	
> ADD >		100GM/BOT	N06383 003	
> ADD >		500GM/BOT	N06383 004	

METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE

> ADD >	AB	LEMMON	50MG	N74141 001	
> ADD >				JAN 31, 1995	
> ADD >	AB		100MG	N74141 002	
> ADD >				JAN 31, 1995	

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

HABITROL

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

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN

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

NITROGLYCERIN

INJECTABLE; INJECTION

NITROSTAT

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

NITROGLYCERIN

INJECTABLE; INJECTION

> DLT >	NITROSTAT				
> ADD >	@ PARKE DAVIS	5MG/ML	N18588 002		
> ADD >			DEC 23, 1983		

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

> ADD >	ZOFRAN IN PLASTIC CONTAINER				
> ADD >	+ GLAXO	EQ 0.64MG BASE/ML	N20403 001		
> ADD >			JAN 31, 1995		

PENICILLAMINE

TABLET; ORAL

> ADD >	DEPEN				
> ADD >	+ WALLACE	250MG	N19854 001		
> DLT >	DEPEN 250				
> DLT >	+ WALLACE	250MG	N19854 001		

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

> ADD >	IONAMIN				
> ADD >	FISONS	EQ 15MG BASE	N11613 004		
> ADD >	+	EQ 30MG BASE	N11613 002		
> DLT >	IONAMIN-15				
> DLT >	FISONS	EQ 15MG BASE	N11613 004		
> DLT >	IONAMIN-30				
> DLT >	+ FISONS	EQ 30MG BASE	N11613 002		

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

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

PROPYLTHIOURACIL

TABLET; ORAL

	PROPYLTHIOURACIL				
> DLT > RD	LILLY	50MG	N06213 001		
> ADD >	@	50MG	N06213 001		

SODIUM CHLORIDE

INJECTABLE; INJECTION

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

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL

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

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

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

TABLET, EXTENDED RELEASE; ORAL

> DLT >	LABID				
> DLT > BC	+ PROCTER AND GAMBLE	250MG	N87225 001		
> ADD >	@	250MG	N87225 001		
	THEOLAIR-SR				
> DLT > BC	3M	250MG	N86363 002		
> DLT >			JUL 16, 1987		
> ADD >		250MG	N86363 002		
> ADD >			JUL 16, 1987		
> ADD >	UNI-DUR				
> ADD > BC	+ KEY PHARMS	400MG	N89822 001		
> ADD >			JAN 04, 1995		

NITROGLYCERIN

INJECTABLE; INJECTION

>DLT>	NITROSTAT				
>ADD>	@ PARKE DAVIS	5MG/ML	N18588 002		
>ADD>			DEC 23, 1983		

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

>ADD>	ZOFRAN IN PLASTIC CONTAINER				
>ADD>	+ GLAXO	EQ 0.64MG BASE/ML	N20403 001		
>ADD>			JAN 31, 1995		

PENICILLAMINE

TABLET; ORAL

>ADD>	DEPEN				
>ADD>	+ WALLACE	250MG	N19854 001		
>DLT>	DEPEN 250				
>DLT>	+ WALLACE	250MG	N19854 001		

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

>ADD>	IONAMIN				
>ADD>	FISONS	EQ 15MG BASE	N11613 004		
>ADD>	+	EQ 30MG BASE	N11613 002		
>DLT>	IONAMIN-15				
>DLT>	FISONS	EQ 15MG BASE	N11613 004		
>DLT>	IONAMIN-30				
>DLT>	+ FISONS	EQ 30MG BASE	N11613 002		

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

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

PROPYLTHIOURACIL

TABLET; ORAL

	PROPYLTHIOURACIL				
>DLT> BD	LILLY	50MG	N06213 001		
>ADD>	@	50MG	N06213 001		

SODIUM CHLORIDE

INJECTABLE; INJECTION

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

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL

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

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

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

TABLET, EXTENDED RELEASE; ORAL

>DLT>	LABID				
>DLT> BC	+ PROCTER AND GAMBLE	250MG	N87225 001		
>ADD>	@	250MG	N87225 001		
	THEOLAIR-SR				
>DLT> BC	3M	250MG	N86363 002		
>DLT>			JUL 16, 1987		
>ADD>		250MG	N86363 002		
>ADD>			JUL 16, 1987		
>ADD>	UNI-DUR				
>ADD> BC	+ KEY PHARMS	400MG	N89822 001		
>ADD>			JAN 04, 1995		

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

UNI-DUR

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

UNIPHYL

>ADD>	BC	PURDUE FREDERICK	400MG	N87571 001	
>ADD>				SEP 01, 1982	

THIOTEPA

INJECTABLE; INJECTION

THIOPLEX

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

THIOTEPA

>DLT>	AP	* IMMUNEX	15MG/VIAL	N11683 001	
>ADD>		+	15MG/VIAL	N11683 001	

VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

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

VANCOMYCIN HYDROCHLORIDE

POWDER FOR RECONSTITUTION; ORAL

VANCOCIN HCL

>DLT>	AB	* LILLY	EQ 500MG BASE/6ML	N61667 001	
>ADD>		+	EQ 500MG BASE/6ML	N61667 001	

VANCOLED

>DLT>	AB	LEDERLE	EQ 500MG BASE/6ML	N63321 003	
>DLT>				OCT 15, 1993	
>ADD>		@	EQ 500MG BASE/6ML	N63321 003	
>ADD>				OCT 15, 1993	

VITAMIN A

CAPSULE; ORAL

VITAMIN A

>DLT>	AA	BANNER PHARMACAPS	50,000 USP UNITS	N83973 001	

VITAMIN A

CAPSULE; ORAL

VITAMIN A

>ADD>		@ BANNER PHARMACAPS	50,000 USP UNITS	N83973 001	

VITAMIN A PALMITATE

CAPSULE; ORAL

VITAMIN A

>DLT>	AA	BANNER PHARMACAPS	EQ 50,000 UNITS BASE	N80702 001	
>ADD>		@	EQ 50,000 UNITS BASE	N80702 001	

VITAMIN A PALMITATE

>DLT>	AA	BANNER PHARMACAPS	EQ 50,000 UNITS BASE	N83948 001	
>ADD>		@	EQ 50,000 UNITS BASE	N83948 001	

INSULIN PORK

INJECTABLE; INJECTION

> DLT <	INSULIN			
> DLT <	+ NOVO NORDISK	100 UNITS/ML		N17926 003
> ADD <	REGULAR INSULIN			
> ADD <	+ NOVO NORDISK	100 UNITS/ML		N17926 003

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION

> DLT <	PROTAMINE ZINC AND ILETIN II			
> DLT <	+ LILLY	100 UNITS/ML		N18476 001
> ADD <	@	100 UNITS/ML		N18476 001
	PROTAMINE ZINC INSULIN			
> DLT <	SQUIBB	100 UNITS/ML		N17928 003
> ADD <	+	100 UNITS/ML		N17928 003

MICONAZOLE NITRATE

CREAM; VAGINAL

	MICONAZOLE NITRATE			
> ADD <	LEMMON	2%		N74136 001
> ADD <				JAN 04, 1995

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 1 / JANUARY '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 1995]

NAME *Generic/Chemical* *TN- Trade Name*	***INDICATION DESIGNATED***	***SPONSOR & ADDRESS*** *DD- Date Designated* *MA- Marketing Approval*
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 / /
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 / /

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

NO JANUARY 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 JANUARY 1995 GUIDANCES

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

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

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

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
1>ADD>	20408 001	DORZOLAMIDE HYDROCHLORIDE; TRUSOPT	4797413	JUN 30, 2004	U-103	NCE	DEC 09, 1999
>ADD>			4619939	OCT 28, 2003	U-104		
>ADD>	20323 001	ESTRADIOL; VIVELLE	5300291	APR 05, 2011		NS	OCT 28, 1997
>ADD>			4994278	FEB 19, 2008			
>ADD>			4994267	FEB 19, 2008			
>ADD>			4814168	MAR 21, 2006			
>ADD>	20323 002	ESTRADIOL; VIVELLE	5300291	APR 05, 2011			
>ADD>			4994278	FEB 19, 2008			
>ADD>			4994267	FEB 19, 2008			
>ADD>			4814168	MAR 21, 2006			
>ADD>	20323 003	ESTRADIOL; VIVELLE	5300291	APR 05, 2011		NS	OCT 28, 1997
>ADD>			4994278	FEB 19, 2008			
>ADD>			4994267	FEB 19, 2008			
>ADD>			4814168	MAR 21, 2006			
>ADD>	20323 004	ESTRADIOL; VIVELLE	5300291	APR 05, 2011			
>ADD>			4994278	FEB 19, 2008			
>ADD>			4994267	FEB 19, 2008			
>ADD>			4814168	MAR 21, 2006			
>ADD>	20303 001	ESTROGENS, CONJUGATED; PREMPRO (PREMARIN;CYCRIN 14/14)	4826831	MAY 02, 2006	U-102	NP	DEC 30, 1997
>ADD>	20460 001	GANCICLOVIR; CYTOVENE	4507305	OCT 19, 1999	U-64	NDF	DEC 22, 1997
>ADD>	19842 001	IBUPROFEN; CHILDREN'S MOTRIN	5374659	DEC 20, 2011			
>ADD>	20135 001	IBUPROFEN; MOTRIN	5320855	JUN 14, 2011			
>ADD>			5215755	JUN 01, 2010		NDF	NOV 16, 1997
>ADD>	20135 002	IBUPROFEN; MOTRIN	5320855	JUN 14, 2011			
>ADD>			5215755	JUN 01, 2010		NDF	NOV 16, 1997
>ADD>	19670 001	LORATADINE; CLARITIN-D	4282233	AUG 04, 2000		NCE	APR 12, 1998
>ADD>	20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		D-20	FEB 02, 1996
>DLT>	~~20007 001~~	~~ONDANSETRON HYDROCHLORIDE; ZOFRAN~~	~~4695578~~	~~JAN 03, 2005~~		~~D-20~~	~~FEB 02, 1996~~
>ADD>	20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		NCE	JAN 04, 1996
>DLT>	~~20103 001~~	~~ONDANSETRON HYDROCHLORIDE; ZOFRAN~~	~~4695578~~	~~JAN 03, 2005~~		~~NCE~~	~~JAN 04, 1996~~
>ADD>	20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		NCE	JAN 04, 1996
>DLT>	~~20103 002~~	~~ONDANSETRON HYDROCHLORIDE; ZOFRAN~~	~~4695578~~	~~JAN 03, 2005~~		~~NCE~~	~~JAN 04, 1996~~
>ADD>	20403 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4753789	JUN 28, 2005	U-44	D-20	FEB 02, 1996
>ADD>			4695578	JAN 04, 2005		NCE	JAN 04, 1996
>ADD>						I-9	AUG 13, 1996

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19901 001	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
>ADD>	19901 002	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
>ADD>	19901 003	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
>ADD>	19901 004	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
>ADD>	20240 001	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3		
>ADD>	20240 002	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3		
>ADD>	20240 003	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3		
>ADD>	20240 004	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3		

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