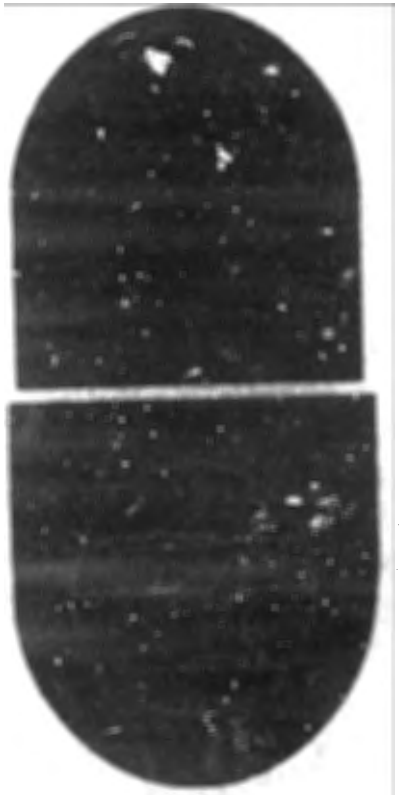
CUMULATIVE SUPPLEMENT 2

JAN'95-FEB'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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

Cumulative Supplement 2

FEBRUARY 1995

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

CUMULATIVE SUPPLEMENT 2

FEBRUARY 1995

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

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

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

Products	Federal Register Reference
Nitroglycerin (capsule, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (film, extended release; transdermal*)	JUL 15, 1993 (58 FR 38129)
Nitroglycerin (tablet, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 05, 1985 (50 FR 27688)

*The Federal Register of July 15, 1993 (58 FR 38129) announced that the FDA was revoking the temporary exemption for nitroglycerin in a transdermal delivery system. Marketing of a drug product that is the subject of a conditionally approved ANDA may continue by meeting the requirements listed in the Federal Register. Firms wishing to submit a new ANDA before a drug product is approved (NDA or ANDA) and appears in the List should submit a 505(b)(2) application following the directions contained in the Federal Register. Nitro-Dur has been selected as the reference listed drug. The preamble to the final rule (57 FR 17958) states if there are multiple NDA's, the reference listed drug generally will be the market leader. This is the basis upon which Nitro-Dur was selected. In addition, the preamble states that, in multiple NDA situations, a product not designated as the reference listed drug and not shown to be bioequivalent to the reference listed drug may be shielded from generic competition. This is the case with Summit's Transderm-Nitro. The Office of Generic Drugs (OGD) has been requested to have a second listed drug as provided for in the Final Rule. OGD has granted this request. Therefore, at the time that Schering's and Summit's supplements are fully approved and their products are entered into the List, we will have two reference listed drugs for the nitroglycerin transdermal systems. Firms may, therefore, elect to conduct bioequivalence studies against either of these products. It is conceivable that a non-referenced listed drug may be fully approved and appear in the List; in this case, the Agency's referenced listed drug will not change and a 505(b)(2) application will be appropriate until the reference listed drugs are fully approved. Once they are fully approved, a 505(j) application will be the appropriate mechanism for an ANDA submission.

1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation

of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will automatically reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. However, when the applicant name change is one which may not be easily recognized or located in the listing (e.g., White Towne Paulsen [Former Abbreviated Name] is changed to Whiteworth Towne [New Abbreviated Name], the name change will appear in this section and will be identified with an asterisk.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
BRIAN PHARMACEUTICALS INC (BRIAN)	HYGENICS PHARMACEUTICALS INC (HYGENICS PHARMS)

1.4 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

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

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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

DEFINITIONS

Drug Product

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

New Molecular Entity

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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

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

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

PRESCRIPTION DRUG PRODUCT LIST
15TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / JAN'95 - FEB'95

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

> ADD >		**ACETAZOLAMIDE SODIUM**				
> ADD >	**AP**	BEDFORD	**EQ 500MG BASE/VIAL**	**N40089 001**		
> ADD >				FEB 28, 1995		
		DIAMOX				
> ADD >	**AP**	+ STORZ OPHTHALM	**EQ 500MG BASE/VIAL**	**N09388 001**		
> ADD >				DEC 05, 1990		

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

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

ASPIRIN; METHOCARBAMOL

TABLET; ORAL

	METHOCARBAMOL AND ASPIRIN			
AB	STEVENS J	**325MG;400MG**	**N81145 001**	
			JAN 31, 1995	

ATENOLOL

TABLET; ORAL

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

ATOVAQUONE

SUSPENSION; ORAL

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

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

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

BUMETANIDE

INJECTABLE; INJECTION

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

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	
	(a)	EQ 20MG BASE/ML	N50581 002	
			SEP 20, 1984	
	(a)	EQ 40MG BASE/ML	N50581 001	
			SEP 20, 1984	

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

TABLET; ORAL
QUESTRAN

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

CIMETIDINE

TABLET; ORAL
CIMETIDINE

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

> DLT > > DLT > > DLT >	UPJOHN	EQ 1% BASE	N50537 002 FEB 22, 1994	

SWAB; TOPICAL
CLEOCIN

> ADD > > ADD > > ADD > > ADD >	UPJOHN	EQ 1% BASE	N50537 002 FEB 22, 1994	

CLOTRIMAZOLE

SOLUTION; TOPICAL
CLOTRIMAZOLE

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

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
RUBRAMIN PC

AP	+ SQUIBB	0.1MG/ML	N06799 002	

CYANOCOBALAMIN

INJECTABLE; INJECTION

RUBRAMIN PC

@ SQUIBB — 0.1MG/ML — N06799 002

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

> ADD > DAUNORUBICIN HCL

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

> ADD >

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

DESMOPRESSIN ACETATE

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

STIMATE

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

DEXAMETHASONE

TABLET; ORAL

HEXADROL

> DLT > BP ORGANON — 0.5MG — N12675 004

> DLT > BP — 0.75MG — N12675 007

> DLT > BP — 1.5MG — N12675 009

> ADD > @ — 0.5MG — N12675 004

> ADD > @ — 0.75MG — N12675 007

> ADD > @ — 1.5MG — N12675 009

DICLOFENAC POTASSIUM

TABLET; ORAL

CATAFLAM

GEIGY — 25MG — N20142 001 NOV 24, 1993

@ — 25MG — N20142 001 NOV 24, 1993

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTAMINE HCL

> ADD > AP ASTRA — EQ 12.5MG BASE/ML — N74098 001 FEB 21, 1995

> ADD >

> ADD > AP SANOFI WINTHROP — EQ 12.5MG BASE/ML — N74292 001 FEB 16, 1995

> ADD >

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DOXORUBICIN HCL

> ADD > AP PHARMACHEMIE (NL) — 2MG/ML — N63336 001 FEB 28, 1995

> ADD >

> ADD > AP — 200MG/100ML — N63336 004 FEB 28, 1995

> ADD >

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

BX — 0.1MG/24HR — N20323 004 OCT 28, 1994

— 0.0375MG/24HR — N20323 001 OCT 28, 1994

— 0.075MG/24HR — N20323 003 OCT 28, 1994

ETOPOSIDE

INJECTABLE; INJECTION

> ADD > TOPOSAR

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

> ADD >

FLUOCINONIDE

SOLUTION; TOPICAL
FLUOCINONIDE
> ADD > AT FOUGERA 0.05% N72934 001 FEB 27, 1995 > DLT >
> ADD >

FLURBIPROFEN SODIUM

SOLUTION/DROPS; OPHTHALMIC
FLURBIPROFEN SODIUM
AT BAUSCH AND LOMB 0.03% N74447 001 JAN 04, 1995 > ADD >

OCUFEN
AT + ALLERGAN 0.03% N19404 001 DEC 31, 1986 > ADD >

GEMFIBROZIL

CAPSULE; ORAL
GEMFIBROZIL
AB MYLAN 300MG N73466 001 JAN 25, 1993 > DLT >

AB + 300MG N73466 001 JAN 25, 1993 > DLT >

LOPID
AB + PARKE DAVIS 300MG N18422 002 > DLT >
@ 300MG N18422 002 > DLT >

TABLET; ORAL
GEMFIBROZIL
> ADD > AB MYLAN 600MG N74452 001 FEB 16, 1995 > ADD >
> ADD >

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE
> ADD > AB WATSON LABS 5MG N74223 001 FEB 27, 1995 > DLT >
> ADD >
> ADD > AB 10MG N74223 002 FEB 27, 1995 > ADD >
> ADD >

GLYBURIDE

TABLET; ORAL
GLUBATE
> DLT >
> DLT > @ HOECHST ROUSSEL 1.5MG N20055 001 APR 17, 1992
> DLT >
> DLT > @ 3MG N20055 002 APR 17, 1992
> DLT >
> ADD >
> ADD > AB HOECHST ROUSSEL 1.5MG N20055 001 APR 17, 1992
> ADD >
> ADD > AB 3MG N20055 002 APR 17, 1992
> ADD >
GLYNASE
> ADD > AB UPJOHN 1.5MG N20051 001 MAR 04, 1992
> ADD >
> ADD > AB 3MG N20051 002 MAR 04, 1992
> ADD >

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 > DLT >
@ SANOFI WINTHROP 25,000 UNITS/ML N18237 001 > ADD >

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

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

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
APRESOLINE-ESIDRIX

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

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR HCT

> ADD >		CIBA	25MG;50MG	N18303 001	DEC 31, 1984
> ADD >			25MG;100MG	N18303 002	DEC 31, 1984
> ADD >	+		50MG;100MG	N18303 003	DEC 31, 1984
> ADD >					
> DLT >		LOPRESSOR HCT 100/25			
> DLT >		CIBA	25MG;100MG	N18303 002	DEC 31, 1984
> DLT >					
> DLT >		LOPRESSOR HCT 100/50			
> DLT >	+	CIBA	50MG;100MG	N18303 003	DEC 31, 1984
> DLT >					
> DLT >		LOPRESSOR HCT 50/25			
> DLT >		CIBA	25MG;50MG	N18303 001	DEC 31, 1984
> DLT >					

HYDROCORTISONE

ENEMA; RECTAL
CORTENEMA

> ADD >	AT	+	SOLVAY	100MG/60ML	N16199 001
> DLT >		+		100MG/60ML	N16199 001

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

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

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

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL
ORUVAIL

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

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON

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

MEBENDAZOLE

TABLET, CHEWABLE; ORAL
MEBENDAZOLE

AB		COPLEY PHARM	100MG	N73580 001	JAN 04, 1995

VERMOX

AB	+	JANSSEN	100MG	N17481 001	

METHADONE HYDROCHLORIDE

POWDER; FOR RX COMPOUNDING
METHADONE HCL

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

METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE

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

NAPROXEN

TABLET; ORAL
NAPROXEN

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

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
HABITROL

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

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
HABITROL

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

> ADD >

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL
NISOCOR

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

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
NITROFURANTOIN

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

NITROGLYCERIN

INJECTABLE; INJECTION
NITROSTAT

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

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ZOFRAN IN PLASTIC CONTAINER

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

PENICILLAMINE

TABLET; ORAL
DEPEN

+	WALLACE	250MG	N19854 001	

DEPEN 250

+	WALLACE	250MG	N19854 001	> ADD >

PERINDOPRIL ERBUMINE

TABLET; ORAL
ACEON

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

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
IONAMIN

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

IONAMIN-15

	FISONS	EQ 15MG BASE	N11613 004	

IONAMIN-30

+	FISONS	EQ 30MG BASE	N11613 002	

PINDOLOL

TABLET; ORAL
PINDOLOL

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

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	> ADD >

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL
KAON CL

	SAVAGE LABS	6.7MEQ	N17046 001	
@		6.7MEQ	N17046 001	

KAON CL-10

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

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

BD	LILLY	50MG	N06213 001	
@		50MG	N06213 001	

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	BAXTER	9MG/ML	N16677 004 OCT 30, 1985	
AP	+	9MG/ML	N16677 004 OCT 30, 1985	

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

		SUCOSTRIN			
> ADD >	AP	APOTHECON	20MG/ML		N08847 001
			100MG/ML		N08847 003
> ADD >		@			
> DLT >	AP	SQUIBB	20MG/ML		N08847 001
> DLT >		@	100MG/ML		N08847 003

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL

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

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

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

TABLET, EXTENDED RELEASE; ORAL

	LABID			
BC	+ PROCTER AND GAMBLE	250MG		N87225 001
	@	250MG		N87225 001
	THEOLAIR-SR			
BC	3M	250MG		N86363 002 JUL 16, 1987
		250MG		N86363 002 JUL 16, 1987
	UNI-DUR			
BC	+ KEY PHARMS	400MG		N89822 001 JAN 04, 1995
	+	600MG		N89823 001 JAN 04, 1995
	UNIPHYL			
BC	PURDUE FREDERICK	400MG		N87571 001 SEP 01, 1982

THIOTEPA

INJECTABLE; INJECTION

	THIOPLEX			
	IMMUNEX	15MG/VIAL		N20058 001 DEC 22, 1994
AP	LEDERLE	15MG/VIAL		N20058 001 DEC 22, 1994
	THIOTEPA			
AP	+ IMMUNEX	15MG/VIAL		N11683 001
	+	15MG/VIAL		N11683 001

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			
AA	BANNER PHARMACAPS	EQ 50,000 UNITS BASE		N83948 001

VITAMIN A PALMITATE

CAPSULE; ORAL
VITAMIN A PALMITATE
@ BANNER PHARMACAPS EQ 50,000 UNITS BASE N83948 001

WARFARIN SODIUM

>ADD> INJECTABLE; INJECTION
>ADD> COUMADIN
>ADD> + DUPONT MERCK 5MG/VIAL N09218 024
>ADD> FEB 07, 1995

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN

> ADD >	ABLE	120MG	N73106 001	
> ADD >			FEB 27, 1995	
> ADD >		325MG	N73107 001	
> ADD >			FEB 27, 1995	
> ADD >		650MG	N73108 001	
> ADD >			FEB 27, 1995	

IBUPROFEN

CAPSULE; ORAL
MIDOL

> DLT >	+ WINTHROP	200MG	N70626 001	
> DLT >			SEP 02, 1987	
> DLT >		200MG	N71002 001	
> DLT >			SEP 02, 1987	
> ADD >	@	200MG	N70626 001	
> ADD >			SEP 02, 1987	
> ADD >	@	200MG	N71002 001	
> ADD >			SEP 02, 1987	

TABLET; ORAL
MIDOL

> DLT >	WINTHROP	200MG	N70591 001	
> DLT >			SEP 02, 1987	
> DLT >		200MG	N71001 001	
> DLT >			SEP 02, 1987	
> ADD >	@	200MG	N70591 001	
> ADD >			SEP 02, 1987	
> ADD >	@	200MG	N71001 001	
> ADD >			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 SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION
PROTAMINE ZINC AND ILETIN II

+	LILLY	100 UNITS/ML	N18476 001
@		100 UNITS/ML	N18476 001

PROTAMINE ZINC INSULIN

	SQUIBB	100 UNITS/ML	N17928 003
+		100 UNITS/ML	N17928 003

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE

	LEMMON	2%	N74136 001
			JAN 04, 1995

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-February 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 / /
CHONDROITINASE TN=	TREATMENT OF PATIENTS UNDERGOING VITRECTOMY.	STORZ OPHTHALMICS AMERICAN CYANAMID COMPANY PEARL RIVER NY 10965 DD 02/09/95 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 / /
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 / /
PURIFIED TYPE II COLLAGEN TN= COLLORAL	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	AUTOIMMUNE, INCORPORATED 128 SPRING STREET LEXINGTON MA 02173 DD 02/09/95 MA / /

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

NO FEBRUARY 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 FEBRUARY 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
NEW INDICATION

I-117	TO SLOW THE PROGRESSION OF CORONARY ATHEROSCLEROSIS IN PATIENTS WITH CORONARY HEART DISEASE

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

BLANK

PAGE

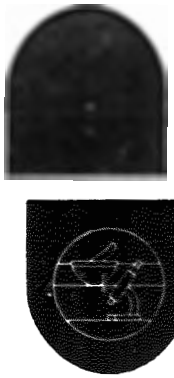
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20500 001	ATOVAQUONE; MEPRON					
>ADD>			5053432	OCT 01, 2008		NCE	NOV 25, 1997
>DLT>	~~18281 001~~	~~CARBAMAZEPINE; TEGRETOL~~	4981874	AUG 15, 2009	U-69	NDF	FEB 08, 1998
>DLT>	~~18927 001~~	~~CARBAMAZEPINE; TEGRETOL~~	~~4400212~~	~~OCT 11, 2000~~			
>DLT>	~~16608 001~~	~~CARBAMAZEPINE; TEGRETOL~~	~~4400212~~	~~OCT 11, 2000~~			
>ADD>	20222 001	COLESTIPOL HYDROCHLORIDE; COLESTID	~~4400212~~	~~OCT 11, 2000~~			
	20303 001	CONJUGATED ESTROGENS; PREMPRO (PREMARIN;CYCRIN 14/14)				NDF	JUL 19, 1997
>ADD>	20287 001	DALTEPARIN SODIUM; FRAGMIN	4826831	MAY 02, 2006	U-102	NP	DEC 30, 1997
	20408 001	DORZOLAMIDE HYDROCHLORIDE; TRUSOPT	4303651	JAN 04, 2000		NCE	DEC 22, 1999
			4797413	JUN 30, 2004	U-103	NCE	DEC 09, 1999
>ADD>	19668 001	DOXAZOSIN MESYLATE; CARDURA	4619939	OCT 28, 2003	U-104		
>ADD>	19668 002	DOXAZOSIN MESYLATE; CARDURA				I-96	FEB 06, 1998
>ADD>	19668 003	DOXAZOSIN MESYLATE; CARDURA				I-96	FEB 06, 1998
>ADD>	19668 004	DOXAZOSIN MESYLATE; CARDURA				I-96	FEB 06, 1998
	20323 001	ESTRADIOL; VIVELLE				I-96	FEB 06, 1998
			5300291	APR 05, 2011		NS	OCT 28, 1997
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
	20323 002	ESTRADIOL; VIVELLE	4814168	MAR 21, 2006			
			5300291	APR 05, 2011			
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
	20323 003	ESTRADIOL; VIVELLE	4814168	MAR 21, 2006			
			5300291	APR 05, 2011		NS	OCT 28, 1997
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
	20323 004	ESTRADIOL; VIVELLE	4814168	MAR 21, 2006			
			5300291	APR 05, 2011			
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
>ADD>	20375 001	ESTRADIOL; CLIMARA	4814168	MAR 21, 2006			
>ADD>	20375 002	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010			
>ADD>	20121 001	FLUTICASONE PROPIONATE; FLONASE	5223261	JUN 29, 2010			
	20460 001	GANCICLOVIR; CYTOVENE				NDF	OCT 19, 1997
	19842 001	IBUPROFEN; CHILDREN'S MOTRIN	4507305	OCT 19, 1999	U-64	NDF	DEC 22, 1997
			5374659	DEC 20, 2011			

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
	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
>ADD>	18956 007	IOHEXOL; OMNIPAQUE 70	4396597	JUL 14, 1998			
>ADD>			4250113	DEC 26, 1999			
>ADD>	19816 002	KETOPROFEN; ORUVAIL				NDF	SEP 24, 1996
>ADD>	19816 003	KETOPROFEN; ORUVAIL				NDF	SEP 24, 1996
	19670 001	LORATADINE; CLARITIN-D	4282233	AUG 04, 2000		NCE	APR 12, 1998
>ADD>	19643 002	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999		I-117	FEB 08, 1998
>ADD>	19643 003	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999		I-117	FEB 08, 1998
>ADD>	19643 004	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999		I-117	FEB 08, 1998
>ADD>	20356 001	NISOLDIPINE; NISOCOR				NCE	FEB 02, 2000
>ADD>	20356 002	NISOLDIPINE; NISOCOR				NCE	FEB 02, 2000
>ADD>	20356 003	NISOLDIPINE; NISOCOR				NCE	FEB 02, 2000
>ADD>	20356 004	NISOLDIPINE; NISOCOR				NCE	FEB 02, 2000
	20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		D-20	FEB 02, 1996
	20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		NCE	JAN 04, 1996
	20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		NCE	JAN 04, 1996
	20403 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4753789	JUN 28, 2005	U-44	D-20	FEB 02, 1996
			4695578	JAN 04, 2005		NCE	JAN 04, 1996
						I-9	AUG 13, 1996
	19901 001	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
	19901 002	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
	19901 003	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
	19901 004	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
	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

New 15th Edition



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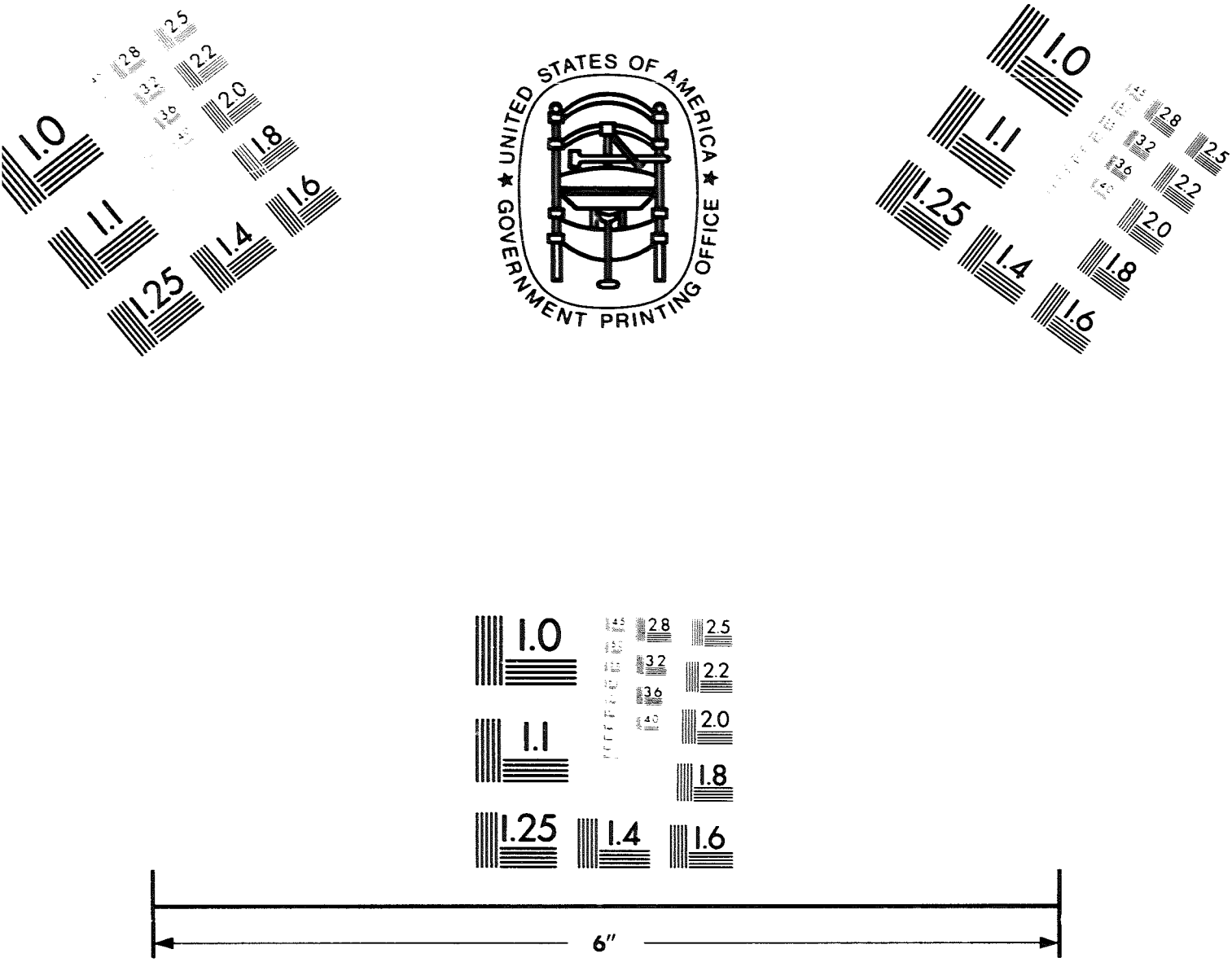
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