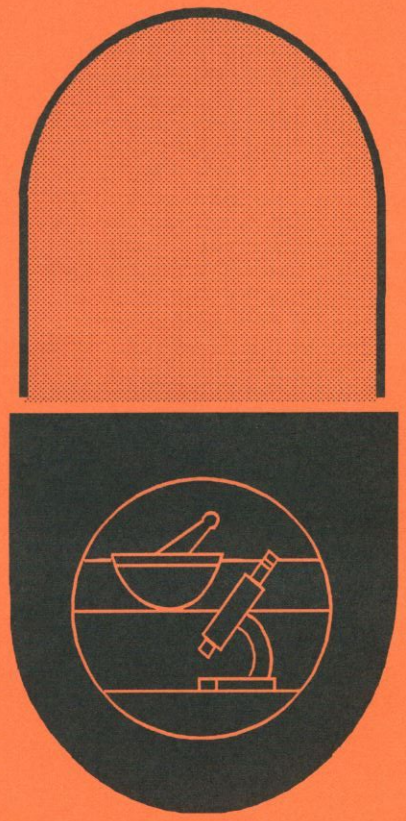
CUMULATIVE SUPPLEMENT 1
JAN'00



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGEMENT AND SERVICES

2000

Approved drug products with therapeutic equivalence

Prepared By
Division of Data Management and Services
Office of Information Technology
Center for Drug Evaluation and Research
Food and Drug Administration

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

Cumulative Supplement 1

JANUARY 2000

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THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

CUMULATIVE SUPPLEMENT 1
JANUARY 2000

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, 20th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

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.)

New additions 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.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol **>DLT>** (DELETE) to the left of the line. 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 (hard copy only) for this edition.

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 20h Edition List will then be added to the "Discontinued Drug Product List" appearing in the 21st Edition.

1.2 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 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

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL)	AVENTIS PHARMACEUTICALS INC (AVENTIS PHARMS)
RHONE POULENC RORER PHARMACEUTICALS INC (RHONE POULENC RORER)	AVENTIS PHARMACEUTICALS PRODUCTS INC (AVENTIS PHARM PROD)

1.3 AVAILABILITY OF THE EDITION

The 20th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is $90.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at http://www.fda.gov/cder/ob. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at
http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the hard copy monthly supplement is at
http://www.fda.gov/cder/orange/supplement/cspreface.htm. Changes to the annual edition are listed separately by month.

There are ASCII text files of the Orange Book drug product data at
http://www.fda.gov/cder/orange/obreadme.htm. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the annual edition or monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 20th annual edition of the 1999 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/20bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at
http://www.fda.gov/cder/orange/supplement/patents.pdf.

The current listing of the Orphan Product Designations and Approvals is available at
http://www.fda.gov/orphan/designat/list.htm.

1.4 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 section 505 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 1999) 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 1999	MAR 2000	JUN 2000	SEP 2000
DRUG PRODUCTS LISTED	10045			
SINGLE SOURCE	2599 (25.9%)			
MULTISOURCE	7335 (73.0%)			
THERAPEUTICALLY EQUIVALENT	6986 (69.5%)			
NOT THERAPEUTICALLY EQUIVALENT	349 (3.5%)			
EXCEPTIONS[1]	111 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	0			
NUMBER OF APPLICANTS	576			

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

> ADD > CALCIUM CHLORIDE

> ADD > INJECTABLE; INJECTION
> ADD > CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER
> ADD > + ABBOTT 100MG/ML N21117 001
> ADD > JAN 28, 2000

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
> ADD > **CARTEOLOL HCL**
> ADD > **AT** ALCON **1%** **N75476 001**
> ADD > JAN 03, 2000
> ADD > **AT** BAUSCH AND LOMB **1%** **N75546 001**
> ADD > JAN 20, 2000

OCUPRESS
> ADD > **AT** + CIBA **1%** **N19972 001**
> ADD > MAY 23, 1990
> DLT > + 1% N19972 001
> DLT > MAY 23, 1990

CEFDINIR

CAPSULE; ORAL
OMNICEF
> ADD > + ABBOTT 300MG N50739 001
> ADD > DEC 04, 1997
> DLT > + PARKE DAVIS 300MG N50739 001
> DLT > DEC 04, 1997

POWDER FOR RECONSTITUTION; ORAL
OMNICEF
> ADD > + ABBOTT 125MG/5ML N50749 001
> ADD > DEC 04, 1997
> DLT > + PARKE DAVIS 125MG/5ML N50749 001
> DLT > DEC 04, 1997

CEFTIBUTEN DIHYDRATE

CAPSULE; ORAL
CEDAX
> ADD > + DJ PHARMA EQ 400MG BASE N50685 002
> ADD > DEC 20, 1995
> DLT > + SCHERING PLOUGH EQ 400MG BASE N50685 002
> DLT > DEC 20, 1995

CEFTIBUTEN DIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
CEDAX
> ADD > DJ PHARMA EQ 90MG BASE/5ML N50686 001
> ADD > DEC 20, 1995
> ADD > + EQ 180MG BASE/5ML N50686 002
> ADD > DEC 20, 1995
> DLT > + SCHERING PLOUGH EQ 90MG BASE/5ML N50686 001
> DLT > DEC 20, 1995
> DLT > + EQ 180MG BASE/5ML N50686 002
> DLT > DEC 20, 1995

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN
> ADD > + HLR EQ 250MG BASE/VIAL N50585 001
> ADD > DEC 21, 1984
> ADD > + EQ 500MG BASE/VIAL N50585 002
> ADD > DEC 21, 1984
> ADD > + EQ 1GM BASE/VIAL N50585 003
> ADD > DEC 21, 1984
> ADD > + EQ 2GM BASE/VIAL N50585 004
> ADD > DEC 21, 1984
> ADD > + EQ 10GM BASE/VIAL N50585 005
> ADD > DEC 21, 1984
> DLT > + ROCHE EQ 250MG BASE/VIAL N50585 001
> DLT > DEC 21, 1984
> DLT > + EQ 500MG BASE/VIAL N50585 002
> DLT > DEC 21, 1984
> DLT > + EQ 1GM BASE/VIAL N50585 003
> DLT > DEC 21, 1984
> DLT > + EQ 2GM BASE/VIAL N50585 004
> DLT > DEC 21, 1984
> DLT > + EQ 10GM BASE/VIAL N50585 005
> DLT > DEC 21, 1984

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER
> ADD > @ HLR EQ 10MG BASE/ML N50624 001
> ADD > FEB 11, 1987
> ADD > + EQ 20MG BASE/ML N50624 002
> ADD > FEB 11, 1987
> ADD > + EQ 40MG BASE/ML N50624 003
> ADD > FEB 11, 1987
> DLT > @ ROCHE EQ 10MG BASE/ML N50624 001
> DLT > FEB 11, 1987
> DLT > + EQ 20MG BASE/ML N50624 002
> DLT > FEB 11, 1987

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

>DLT>	+	ROCHE	EQ 40MG BASE/ML	N50624 003	
>DLT>				FEB 11, 1987	

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION
ROCEPHIN KIT

>ADD>	+	HLR	EQ 1GM BASE/VIAL,N/A;N/A,		
>ADD>			1%	N50585 006	
>ADD>				MAY 08, 1996	
>ADD>	+		EQ 500MG BASE/VIAL,N/A;N/A,		
>ADD>			1%	N50585 007	
>ADD>				MAY 08, 1996	
>DLT>	+	ROCHE	EQ 1GM BASE/VIAL,N/A;N/A,		
>DLT>			1%	N50585 006	
>DLT>				MAY 08, 1996	
>DLT>	+		EQ 500MG BASE/VIAL,N/A;N/A,		
>DLT>			1%	N50585 007	
>DLT>				MAY 08, 1996	

>ADD> CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL
EVOXAC

>ADD>	+	SNOWBRAND	EQ 30MG BASE	N20989 002	
>ADD>				JAN 11, 2000	

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
CLEOCIN T

>ADD>	**AB**	+ PHARMACIA AND UPJOHN	**EQ 1% BASE**	**N50615 001**	
>ADD>				JAN 07, 1987	
>DLT>		+	EQ 1% BASE	N50615 001	
>DLT>				JAN 07, 1987	
>ADD>		**CLINDAMYCIN PHOSPHATE**			
>ADD>	**AB**	ALTANA	**EQ 1% BASE**	**N64160 001**	
>ADD>				JAN 28, 2000	

CROMOLYN SODIUM

SOLUTION; INHALATION
CROMOLYN SODIUM

>ADD>	**AN**	STERIPAK	**10MG/ML**	**N75271 001**	
>ADD>				JAN 18, 2000	

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL

>ADD>	**AT**	ALCON UNIVERSAL	**1%**	**N89162 001**	
>ADD>				JAN 24, 1991	
>DLT>	**AT**	STERIS	**1%**	**N89162 001**	
>DLT>				JAN 24, 1991	

CYCLOSPORINE

CAPSULE; ORAL
CYCLOSPORINE

>ADD>	**AB**	EON	**25MG**	**N65017 002**	
>ADD>				JAN 13, 2000	
>ADD>	**AB**		**100MG**	**N65017 001**	
>ADD>				JAN 13, 2000	
		NEORAL			
>ADD>	**AB**	NOVARTIS	**25MG**	**N50715 001**	
>ADD>				JUL 14, 1995	
>ADD>	**AB**	+	**100MG**	**N50715 002**	
>ADD>				JUL 14, 1995	
>DLT>	**BX**		25MG	N50715 001	
>DLT>				JUL 14, 1995	
>DLT>	**BX**	+	100MG	N50715 002	
>DLT>				JUL 14, 1995	

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL

>ADD>	**AP**	+ BEDFORD	**EQ 5MG BASE/ML**	**N50731 001**	
>ADD>				JAN 30, 1998	
>DLT>		+	EQ 5MG BASE/ML	N50731 001	
>DLT>				JAN 30, 1998	
>ADD>	**AP**	GENSIA SICOR PHARMS	**EQ 5MG BASE/ML**	**N65035 001**	
>ADD>				JAN 24, 2000	

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

> ADD >	AT	ALCON UNIVERSAL	0.1%;EQ 3.5MG BASE/ML;		
> ADD >			10,000 UNITS/ML	N62721 001	
> ADD >				NOV 17, 1986	
> DLT >	AT	STERIS	0.1%;EQ 3.5MG BASE/ML;		
> DLT >			10,000 UNITS/ML	N62721 001	
> DLT >				NOV 17, 1986	

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC, OTIC

DEXAMETHASONE SODIUM PHOSPHATE

> ADD >	AT	ALCON UNIVERSAL	EQ 0.1% PHOSPHATE	N88771 001
> ADD >				JAN 16, 1985

SOLUTION/DROPS; OPHTHALMIC, OTIC

DEXAMETHASONE SODIUM PHOSPHATE

> DLT >	AT	STERIS	EQ 0.1% PHOSPHATE	N88771 001
> DLT >				JAN 16, 1985

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

> ADD >	AT	ALCON UNIVERSAL	EQ 0.1% PHOSPHATE;	
> ADD >			EQ 3.5MG BASE/ML	N62714 001
> ADD >				JUL 21, 1986
> DLT >	AT	STERIS	EQ 0.1% PHOSPHATE;	
> DLT >			EQ 3.5MG BASE/ML	N62714 001
> DLT >				JUL 21, 1986

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HCL

> ADD >	AB3	BIOVAIL	120MG	N20939 001
> ADD >				JAN 28, 2000
> ADD >	AB3		180MG	N20939 002
> ADD >				JAN 28, 2000
> ADD >	AB3		240MG	N20939 003
> ADD >				JAN 28, 2000
> ADD >	AB3		300MG	N20939 004
> ADD >				JAN 28, 2000

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

ETHAMOLIN

> DLT >	+	CYPROS	50MG/ML	N19357 001
> DLT >				DEC 22, 1988
> ADD >	+	QUESTCOR PHARM	50MG/ML	N19357 001
> ADD >				DEC 22, 1988

FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

> ADD >	AP	GENSIA SICOR PHARMS	50MG/ML	N40333 001
> ADD >				JAN 27, 2000

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

> ADD >	AT	ALCON UNIVERSAL	EQ 0.3% BASE	N62523 001
> ADD >				NOV 25, 1985
> DLT >	AT	STERIS	EQ 0.3% BASE	N62523 001
> DLT >				NOV 25, 1985

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

> DLT >		@ STERIS	100 UNITS/ML	N17064 001
> ADD >		@	100 UNITS/ML	N17064 001

HEPARIN SODIUM

> DLT >	AP	STERIS	5,000 UNITS/ML	N17064 003
> DLT >	AP		10,000 UNITS/ML	N17064 004
> DLT >	AP		20,000 UNITS/ML	N17064 005
> DLT >	AP		40,000 UNITS/ML	N17064 006
> ADD >		@	5,000 UNITS/ML	N17064 003
> ADD >		@	10,000 UNITS/ML	N17064 004
> ADD >		@	20,000 UNITS/ML	N17064 005
> ADD >		@	40,000 UNITS/ML	N17064 006

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

>ADD>		**HYDROCHLOROTHIAZIDE**			
>ADD>	**AB**	MYLAN	**12.5MG**	**N75640 001**	
>ADD>				JAN 28, 2000	
		MICROZIDE			
>ADD>	**AB**	+ WATSON LABS	**12.5MG**	**N20504 001**	
>ADD>				DEC 27, 1996	
>DLT>		+	12.5MG	N20504 001	
>DLT>				DEC 27, 1996	

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

		NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE			
>ADD>	**AT**	ALCON UNIVERSAL	**1%;EQ 3.5MG BASE/ML;**		
>ADD>			**10,000 UNITS/ML**	**N62874 001**	
>ADD>				MAY 11, 1988	
>DLT>	**AT**	STERIS	**1%;EQ 3.5MG BASE/ML;**		
>DLT>			**10,000 UNITS/ML**	**N62874 001**	
>DLT>				MAY 11, 1988	

SUSPENSION/DROPS; OTIC

		NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE			
>ADD>	**AT**	ALCON UNIVERSAL	**1%;EQ 3.5MG BASE/ML;**		
>ADD>			**10,000 UNITS/ML**	**N62488 001**	
>ADD>				NOV 06, 1985	
>DLT>	**AT**	STERIS	**1%;EQ 3.5MG BASE/ML;**		
>DLT>			**10,000 UNITS/ML**	**N62488 001**	
>DLT>				NOV 06, 1985	

INULIN

INJECTABLE; INJECTION

INULIN AND SODIUM CHLORIDE

>DLT>	+	CYPROS	100MG/ML	N02282 001
>ADD>	+	QUESTCOR PHARM	100MG/ML	N02282 001

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION

GLOFIL-125

>DLT>		CYPROS	250-300 uCi/ML	N17279 001
>ADD>		QUESTCOR PHARM	250-300 uCi/ML	N17279 001

METAPROTERENOL SULFATE

SYRUP; ORAL

		METAPROTERENOL SULFATE			
>ADD>	**AA**	NOVEX	**10MG/5ML**	**N75235 001**	
>ADD>				JAN 27, 2000	

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

		MORPHINE SULFATE			
>ADD>	**AB**	ESI LEDERLE	**15MG**	**N75407 001**	
>ADD>				JAN 28, 2000	

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

SANDOSTATIN

>DLT>		NOVARTIS	EQ 0.2MG BASE/ML	N19667 004	
>DLT>				JUN 12, 1991	
>DLT>			EQ 1MG BASE/ML	N19667 005	
>DLT>				JUN 12, 1991	
>ADD>	+		EQ 0.2MG BASE/ML	N19667 004	
>ADD>				JUN 12, 1991	
>ADD>	+		EQ 1MG BASE/ML	N19667 005	
>ADD>				JUN 12, 1991	

SANDOSTATIN LAR

>DLT>		NOVARTIS	EQ 10MG BASE/VIAL	N21008 001	
>DLT>				NOV 25, 1998	
>DLT>			EQ 20MG BASE/VIAL	N21008 002	
>DLT>				NOV 25, 1998	
>ADD>	+		EQ 10MG BASE/VIAL	N21008 001	
>ADD>				NOV 25, 1998	
>ADD>	+		EQ 20MG BASE/VIAL	N21008 002	
>ADD>				NOV 25, 1998	

OXCARBAZEPINE

TABLET; ORAL

TRILEPTAL

>ADD>		NOVARTIS	150MG	N21014 001
>ADD>				JAN 14, 2000
>ADD>			300MG	N21014 002
>ADD>				JAN 14, 2000
>ADD>	+		600MG	N21014 003
>ADD>				JAN 14, 2000

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

>DLT>		ROXICODONE			
>DLT>	BX	ROXANE	10MG	N20932 001	
>DLT>				OCT 26, 1998	
>DLT>		+	30MG	N20932 002	
>DLT>				OCT 26, 1998	
>ADD>		@	10MG	N20932 001	
>ADD>				OCT 26, 1998	
>ADD>		@	30MG	N20932 002	
>ADD>				OCT 26, 1998	

PREDNISOLONE

SYRUP; ORAL

		PREDNISOLONE			
>ADD>	**AA**	COPLEY PHARM	**15MG/5ML**	**N40322 001**	
>ADD>				JAN 19, 2000	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

		PREDNISOLONE SODIUM PHOSPHATE			
>ADD>	**AT**	ALCON UNIVERSAL	**EQ 0.11% PHOSPHATE**	**N81043 001**	
>ADD>				OCT 24, 1991	
>ADD>	**AT**		**EQ 0.9% PHOSPHATE**	**N81044 001**	
>ADD>				OCT 24, 1991	
>DLT>	**AT**	STERIS	**EQ 0.11% PHOSPHATE**	**N81043 001**	
>DLT>				OCT 24, 1991	
>DLT>	**AT**		**EQ 0.9% PHOSPHATE**	**N81044 001**	
>DLT>				OCT 24, 1991	

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

		SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE			
>ADD>	**AT**	ALCON UNIVERSAL	**EQ 0.23% PHOSPHATE;10%**	**N73630 001**	
>ADD>				MAY 27, 1993	
>DLT>	**AT**	STERIS	**EQ 0.23% PHOSPHATE;10%**	**N73630 001**	
>DLT>				MAY 27, 1993	

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

		SULFACETAMIDE SODIUM			
>ADD>	**AT**	ALCON UNIVERSAL	**10%**	**N89560 001**	
>ADD>				OCT 18, 1988	
>DLT>	**AT**	STERIS	**10%**	**N89560 001**	
>DLT>				OCT 18, 1988	

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL

		PRIMSOL			
>DLT>		ASCENT PEDS	EQ 25MG BASE/5ML	N74374 001	
>DLT>				JUN 23, 1995	
>ADD>		+	EQ 25MG BASE/5ML	N74374 001	
>ADD>				JUN 23, 1995	
>ADD>		+	EQ 50MG BASE/5ML	N74973 001	
>ADD>				JAN 24, 2000	

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

		TROPICAMIDE			
>ADD>	**AT**	ALCON UNIVERSAL	**1%**	**N89172 001**	
>ADD>				DEC 28, 1990	
>DLT>	**AT**	STERIS	**1%**	**N89172 001**	
>DLT>				DEC 28, 1990	

IBUPROFEN

CAPSULE; ORAL
IBUPROFEN

> DLT >	~~PHARM FORM~~	~~200MG~~	~~N74782 001~~	
> DLT >			~~JUL 06, 1998~~	
> ADD >	+	200MG	N74782 001	
> ADD >			JUL 06, 1998	

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL
LOPERAMIDE HCL

> ADD >	PERRIGO	2MG	N75232 001	
> ADD >			JAN 06, 2000	

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE

> ADD >	CHELSEA LABS	EQ 75MG BASE	N75212 001	
> ADD >			JAN 14, 2000	
> ADD >	GENPHARM	EQ 75MG BASE	N75497 001	
> ADD >			JAN 14, 2000	
> ADD >	RANBAXY	EQ 75MG BASE	N75132 001	
> ADD >			JAN 14, 2000	
> ADD >		EQ 75MG BASE	N75254 001	
> ADD >			JAN 14, 2000	
> ADD >	ZENITH GOLDLINE	EQ 75MG BASE	N75296 001	
> ADD >			JAN 14, 2000	

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST

CUMULATIVE SUPPLEMENT NUMBER 1 JAN '00

NO JANUARY 2000 APPROVALS

This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Product Designations and Approvals List
January 2000

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
1-(11-dodecylamino-10-hydroxyundecyl)-3,7-dimethylxanthine hydrogen methanesulfonate TN=	Treatment of hormone refractory prostate carcinoma.	Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle, WA 98119 DD=01/18/2000
Levodopa and carbidopa TN= Duodopa	Treatment of late stage Parkinson's disease.	Nouvel Pharma, Inc. 11322 Acuff La. Lenexa, KS 66215 DD=01/18/2000
Natural human lymphoblastoid interferon-alpha TN=	Treatment of Behcet's disease.	Amarillo Biosciences, Inc. 800 West Ninth Avenue Amarillo, TX 79101 DD=01/18/2000
Phenylbutyrate TN=	Treatment of acute promyelocytic leukemia.	Elan Corporation 1300 Gould Dr. Gainesville, GA 30504 DD=01/19/2000
Vapreotide TN= Octastatin	Treatment of gastrointestinal and pancreatic fistulas.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland, CH DD=01/10/2000
Vapreotide TN= Octastatin	Treatment of esophageal variceal hemorrhage patients with portal hypertension.	Debiopharm S.A. 17 rue des Terreau CH-1000 LausanÇãne 9 Switzerland, CH DD=01/10/2000

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

NO JANUARY 2000 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021107 001	ALOSETRON HYDROCHLORIDE;LOTRONEX				NCE	FEB 09, 2005
>ADD>	020221 001	AMIFOSTINE;ETHYOL				I-283	JUN 24, 2002
>ADD>	020221 002	AMIFOSTINE;ETHYOL				I-283	JUN 24, 2002
>ADD>	021055 001	BEXAROTENE;TARGRETIN				ODE	DEC 29, 2006
>ADD>	020989 002	CEVIMELINE HYDROCHLORIDE;EVOXAC	4855290	AUG 08, 2006		NCE	JAN 11, 2005
>ADD>			5340821	AUG 23, 2011	U-309		
>ADD>			5580880	JUN 06, 2015	U-310		
>ADD>	019221 001	ENALAPRIL MALEATE;VASERETIC	4472380	SEP 18, 2001			
>ADD>			4374829	FEB 22, 2000			
>ADD>			4374829*PED	AUG 22, 2000			
>ADD>			4472380*PED	MAR 18, 2002			
>ADD>	019221 003	ENALAPRIL MALEATE;VASERETIC	4472380	SEP 18, 2001			
>ADD>			4374829	FEB 22, 2000			
>ADD>			4374829*PED	AUG 22, 2000			
>ADD>			4472380*PED	MAR 18, 2002			
>ADD>	018998 001	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
>ADD>			4374829*PED	AUG 22, 2000			
>ADD>	018998 002	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
>ADD>			4374829*PED	AUG 22, 2000			
>ADD>	018998 003	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
>ADD>			4374829*PED	AUG 22, 2000			
>ADD>	018998 005	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
>ADD>			4374829*PED	AUG 22, 2000			
>ADD>	019309 001	ENALAPRILAT;VASOTEC	4374829	FEB 22, 2000			
>ADD>			4374829*PED	AUG 22, 2000			
>ADD>	021040 001	ESTRADIOL;ORTHO-PREFEST	5108995	APR 28, 2009	U-311		
>ADD>			5382573	JAN 17, 2012			
>ADD>	020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6037353	MAR 14, 2017	U-138		
>ADD>	020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA				NDF	FEB 25, 2003
>ADD>	020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA				NDF	FEB 25, 2003
>ADD>	020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA				NDF	FEB 25, 2003
>ADD>	020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	6037353	MAR 14, 2017	U-138		
>ADD>	020235 001	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-86	PED	MAR 29, 2002
>ADD>			5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
>ADD>			4894476*PED	NOV 02, 2008			
>ADD>			4087544*PED	JUL 16, 2000	U-86		
>ADD>			5084479*PED	JUL 02, 2010	U-125		
>ADD>			4894476	MAY 02, 2008			
>ADD>	020235 002	GABAPENTIN;NEURONTIN	4894476	MAY 02, 2008		PED	MAR 29, 2002
>ADD>			5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
>ADD>			4087544	JAN 16, 2000	U-86		
>ADD>			5084479*PED	JUL 02, 2010	U-125		
>ADD>			4894476*PED	NOV 02, 2008			
>ADD>			4087544*PED	JUL 16, 2000	U-86		
>ADD>	020235 003	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-86	PED	MAR 29, 2002
>ADD>			5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
>ADD>			4894476	MAY 02, 2008			
>ADD>			4087544*PED	JUL 16, 2000	U-86		
>ADD>			5084479*PED	JUL 02, 2010			
>ADD>			4894476*PED	NOV 02, 2008			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020882 001	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
>ADD>			4894476	MAY 02, 2008			
>ADD>			5084479	JAN 02, 2010	U-258		
>ADD>			5084479*PED	JUL 02, 2010	U-258		
>ADD>			4087544*PED	JUL 16, 2000	U-106		
>ADD>			4894476*PED	NOV 02, 2008			
>ADD>	020882 002	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
>ADD>			4894476	MAY 02, 2008			
>ADD>			5084479	JAN 02, 2010	U-258		
>ADD>			4087544*PED	JUL 16, 2000	U-106		
>ADD>			4894476*PED	NOV 02, 2008			
>ADD>			5084479*PED	JUL 02, 2010	U-258		
>ADD>	020460 002	GANCICLOVIR;CYTOVENE	4507305	MAY 21, 2001	U-64		
>ADD>			4423050	MAY 21, 2001	U-64		
>ADD>			4355032	JUN 23, 2003	U-64		
>ADD>			4642346	JUN 24, 2005			
>ADD>	020125 001	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
>ADD>	020125 002	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
>ADD>	020125 003	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
>ADD>	019778 001	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001			
>ADD>	019778 002	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001			
>ADD>	019778 003	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001	U-3		
>ADD>	021088 001	LEUPROLIDE ACETATE;VIADUR				NP	MAR 03, 2003
>ADD>	019558 001	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
>ADD>	019558 002	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
>ADD>	019558 003	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
>ADD>	019558 004	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
>ADD>	019558 006	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
>ADD>	019777 001	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
>ADD>	019777 002	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
>ADD>	019777 003	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
>ADD>	019777 004	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
>ADD>	019777 005	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
>ADD>	019777 006	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
>ADD>	020152 001	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
>ADD>	020152 002	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
>ADD>	020152 003	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
>ADD>	020152 004	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
>ADD>	020152 005	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
>ADD>	020152 006	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
>ADD>	020819 001	PARICALCITOL;ZEMPLAR	5246925	SEP 21, 2010			
>ADD>			5587497	DEC 24, 2013			
>ADD>	021084 001	PERFLUOROPOLYMETHYLISOPROPYL ETHER;SKIN EXPOSURE REDUCTION PASTE AGA				NCE	FEB 17, 2005
>ADD>	019898 002	PRAVASTATIN SODIUM;PRAVACHOL				I-287	FEB 10, 2003
>ADD>						I-286	JAN 18, 2003
>ADD>						D-51	JAN 18, 2003
>ADD>	019898 003	PRAVASTATIN SODIUM;PRAVACHOL				I-287	FEB 10, 2003
>ADD>						I-286	JAN 18, 2003
>ADD>						D-51	JAN 18, 2003

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	019898 004	PRAVASTATIN SODIUM;PRAVACHOL				I-287	FEB 10, 2003
>ADD>						I-286	JAN 18, 2003
>ADD>						D-51	JAN 18, 2003
>ADD>	019157 001	PREDNISOLONE SODIUM PHOSPHATE;PEDIAPRED	4448774	DEC 22, 2002			
>ADD>	020630 001	REMIFENTANIL HYDROCHLORIDE;ULTIVA				NPP	OCT 15, 2002
>ADD>	020630 002	REMIFENTANIL HYDROCHLORIDE;ULTIVA				NPP	OCT 15, 2002
>ADD>	020630 003	REMIFENTANIL HYDROCHLORIDE;ULTIVA				NPP	OCT 15, 2002
>ADD>	020588 001	RISPERIDONE;RISPERDAL	5453425	JUL 11, 2014			
>ADD>			5616587	JUL 11, 2014			
>ADD>	020990 001	SERTRALINE HYDROCHLORIDE;ZOLOFT	4536518	DEC 30, 2005	U-286		
>ADD>			4940731	AUG 30, 2009	U-312		
>ADD>	019721 001	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
>ADD>	019721 002	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
>ADD>	019676 001	SOMATROPIN RECOMBINANT;NUTROPIN				M-2	DEC 01, 2002
>ADD>	019676 002	SOMATROPIN RECOMBINANT;NUTROPIN				M-2	DEC 01, 2002
>ADD>	020522 001	SOMATROPIN RECOMBINANT;NUTROPIN AQ				M-2	DEC 01, 2002
>ADD>	021151 001	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
>ADD>	021151 002	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
>ADD>	021151 003	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
>ADD>	020326 001	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			
>ADD>	020326 002	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			

PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 20TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

ABBREVIATIONS

NPP	**NEW PATIENT POPULATION**

REFERENCES

NEW DOSING SCHEDULE

D-51	**OPTIONAL STARTING DOSE OF 40MG/DAY**

NEW INDICATION

I-283	**TO REDUCE THE INCIDENCE OF MODERATE TO SEVERE XEROSTOMIA IN PATIENTS UNDERGOING POST-OPERATIVE RADIATION TREATMENT FOR HEAD AND NECK CANCER, WHERE THE RADIATION PORT INCLUDES A SUBSTANTIAL PORTION OF THE PAROTID GLANDS**
I-286	**TREATMENT OF PATIENTS WITH FREDERICKSON TYPE III**
I-287	**USE OF PRAVASTATIN IN PATIENTS WITH EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH**
I-288	**CHANGES SEVERAL SECTIONS OF THE PACKAGE INSERT TO INCORPORATE STATEMENTS CONCERNING THE USE OF HIGH DOSES OF LISINOPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE**

MISCELLANEOUS EXCLUSIVITY CODES

M-2	**APPROVAL FOR ADDTION TO CLINICAL PHARMACOLOGY SECTION OF THE LABEL REGARDING (1) IMPROVEMENT IN BONE MINERAL DENSITY IN CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENT PATIENTS AND (2) INCREASES IN SERUM ALKALINE PHOSPHATASE**

PATENT USE CODE

U-309	**TREATING SJOEGREN SYNDROME**
U-310	**TREATMENT OF XEROSTOMIA**
U-311	**HORMONE REPLACEMENT**
U-312	**PANIC DISORDER OBSESSIVE-COMPULSIVE DISORDER POSTTRAUMATIC STRESS DISORDER**