C499-K-03

NDA 075-956/S-001

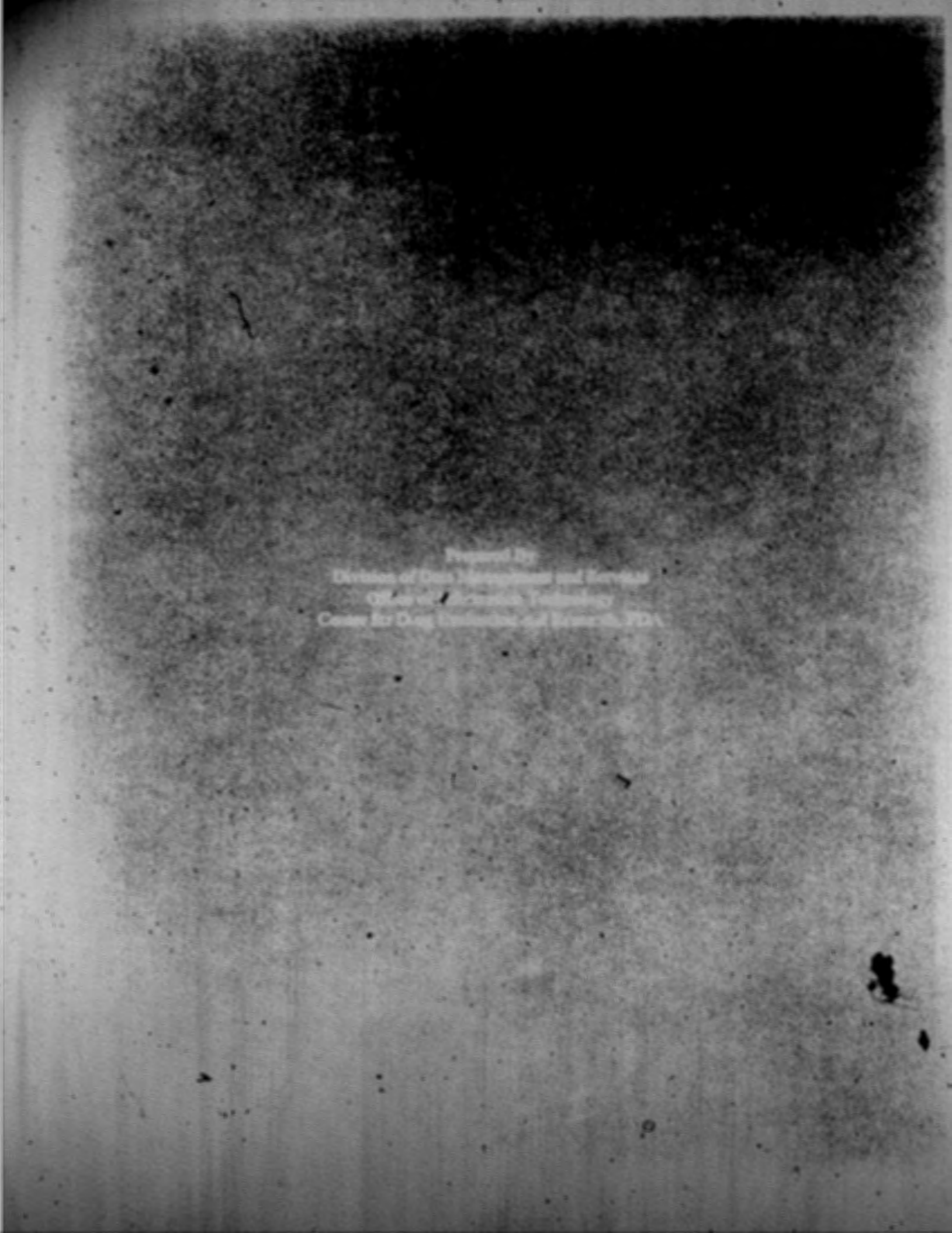
CUMULATIVE
SUPPLEMENT 1
JAN'98

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

18TH EDITION

NDA-CC3976



APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

18TH EDITION

Cumulative Supplement 1

JANUARY 1998

CONTENTS

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

18TH EDITION

CUMULATIVE SUPPLEMENT 1
JANUARY 1998

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, 18th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, OTC Drug Product List, and the Patent and Exclusivity Data 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. However, the overstruck data in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements (hard copy).

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 18th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 19th 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 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 PLSN [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)

NO APPLICANT NAME CHANGES - JANUARY 1998

1.3 ACYCLOVIR 200MG TABLET-REFERENCE LISTED DRUG

Novopharm's single source acyclovir tablets have been declared to be a reference listed drug for the 200 mg tablet in addition to the acylcovir (Zovirax) 800 mg tablet of the innovator. A generic firm wishing to submit an ANDA for a duplicate of the 200 mg acyclovir tablet will be eligible for a waiver of the *in vivo* determination of bioequivalence (1) if their product is proportionally similar in its active and inactive ingredients to their own 800 mg acyclovir tablet and (2) by doing an acceptable comparative dissolution test (dissolution profile) against Novopharm's 200 mg acyclovir reference listed drug.

Before a waiver of the *in vivo* determination of bioequivalence can be granted for the 200 mg acyclovir tablet, the generic firm must have completed an acceptable fasting and fed study comparing their acyclovir 800 mg tablet against the Zovirax 800 mg tablet.

For further information on the study designs, you should contact the Division of Bioequivalence, Office of Generic Drugs.

1.4 FOLLITROPIN ALFA AND BETA

Based on available data derived from physico-chemical tests and bioassay, follitropin alfa and follitropin beta are indistinguishable.

1.5 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 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.

The following *Approved Drug Products with Therapeutic Equivalence Evaluations* files are available on Internet: Prescription Drug Product List; OTC Drug Products; Discontinued Drug Products; Prescription and OTC Drug Product Patent and Exclusivity Data; and Appendices.

These files may be accessed on the Internet's World Wide Web. To access the CDER Home Page, use this Uniform Resource Locator (URL): http://www.fda.gov/cder. You do not need an Internet connection to reach the FDA Home Page; you can use the free dial-up connection (800) 222-0185 for text based, non-graphical use only. For further assistance, please call (301) 443-4908.

The Prescription Drug Products and OTC Drug Product files will be available on a monthly basis in the near future.

1.6 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 1997) 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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1997	MAR 1998	JUN 1998	SEP 1998
DRUG PRODUCTS LISTED	9624			
SINGLE SOURCE	2462 (25.6%)			
MULTISOURCE	7052 (73.3%)			
THERAPEUTICALLY EQUIVALENT	6673 (69.3%)			
NOT THERAPEUTICALLY EQUIVALENT	379 (4.0%)			
EXCEPTIONS[1]	110 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	551			

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

ACARBOSE

TABLET; ORAL
PRECOSE

> DLT >		● [redacted]	25MG	[redacted]	> DLT >		[redacted]
> DLT >				MAY 29, 1997			
> ADD >			25MG	N20482 004			
> ADD >				MAY 29, 1997			

ACETAMINOPHEN; OXYCODONE

CAPSULE; ORAL
OXYCODONE AND ACETAMINOPHEN

> ADD >	AA	HALSEY	500MG;5MG	N40219 001	> DLT >		[redacted]
> ADD >				JAN 22, 1998	> DLT >		
					> ADD >	+	EQ 5MG BASE/ML
					> ADD >		

N18700 001
JUL 31, 1984

ACYCLOVIR

TABLET; ORAL
ACYCLOVIR

> DLT >		● [redacted]	200MG	[redacted]	> DLT >	AT	AKORN
> DLT >				APR 22, 1997	> DLT >		
> ADD >		●	200MG	N74556 001	> ADD >		
> ADD >				APR 22, 1997	> ADD >		
					> ADD >		

[redacted]
500 UNITS/GM;
10,000 UNITS/GM

M64028 001
JAN 30, 1995

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

> ADD >	AT	HI TECH PHARMA	EQ 0.5% BASE	N74543 001	> ADD >		
> ADD >				JAN 15, 1998	> ADD >	AB	LEK PHARM
					> ADD >		

EQ 2.5MG BASE

M74631 001
JAN 13, 1998

SYRUP; ORAL
ALBUTEROL SULFATE

> ADD >	AA	HI TECH PHARMA	EQ 2MG BASE/5ML	N74749 001			
> ADD >				JAN 30, 1998			

PARLODEL

					> ADD >	AB	+ NOVARTIS

EQ 2.5MG BASE

M17962 001

ALPROSTADIL

INJECTABLE; INJECTION
ALPROSTADIL

> ADD >	AP	BEDFORD	0.5MG/ML	N74815 001	> DLT >		[redacted]
> ADD >				JAN 20, 1998	> DLT >		
					> DLT >		
					> ADD >	+	SHIRE

200MG

M20712 001
SEP 30, 1997

PROSTIN VR PEDIATRIC

> ADD >	AP	+ PHARMACIA AND UPJOHN	0.5MG/ML	N18484 001	> DLT >		[redacted]

ALPROSTADIL

INJECTABLE; INJECTION
PROSTIN VR PEDIATRIC

					> DLT >	+	[redacted]

[redacted]

N18484 001

AMRINONE LACTATE

INJECTABLE; INJECTION
INOCOR

					> DLT >		[redacted]
					> DLT >		
					> ADD >	+	EQ 5MG BASE/ML
					> ADD >		

[redacted]

N18700 001
JUL 31, 1984

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
BACITRACIN ZINC AND POLYMYXIN B SULFATE

					> DLT >	AT	AKORN
					> DLT >		
					> DLT >		
					> ADD >		
					> ADD >		
					> ADD >		

[redacted]
500 UNITS/GM;
10,000 UNITS/GM

M64028 001
JAN 30, 1995

BROMOCRIPTINE MESYLATE

TABLET; ORAL
BROMOCRIPTINE MESYLATE

					> ADD >	AB	LEK PHARM
					> ADD >		
					> ADD >		

EQ 2.5MG BASE

M74631 001
JAN 13, 1998

PARLODEL

					> ADD >	AB	+ NOVARTIS

EQ 2.5MG BASE

M17962 001

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE; ORAL
CARBATROL

					> DLT >		[redacted]
					> DLT >		
					> DLT >		[redacted]
					> DLT >		
					> ADD >	+	SHIRE

200MG

M20712 001
SEP 30, 1997

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE; ORAL
CARBATROL

>ADD>		+ SHIRE	300MG	N20712 002	
>ADD>				SEP 30, 1997	

CHLORDIAZEPOXIDE

TABLET; ORAL
LIBRITABS

>ADD>		+ ICN	5MG	N85482 001
>ADD>		●	10MG	N85481 001
>ADD>		●	25MG	N85488 001
>DLT>		[redacted]	[redacted]	[redacted]
>DLT>		[redacted]	[redacted]	[redacted]
>DLT>		[redacted]	[redacted]	[redacted]

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
LIBRIUM

>ADD>	AB		ICN	5MG	N85461 001
>ADD>	AB			10MG	N85472 001
>ADD>	AB	+		25MG	N85475 001
>DLT>	[redacted]		[redacted]	[redacted]	[redacted]
>DLT>	[redacted]			[redacted]	[redacted]
>DLT>	[redacted]			[redacted]	[redacted]

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
PERIDEX

>DLT>	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
>DLT>					
>ADD>	AT	+	ZILA	0.12%	N19028 001
>ADD>					AUG 13, 1986

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
CROLOM

>ADD>	AT		BAUSCH AND LOMB	4%	N74443 001
>ADD>					JAN 30, 1995

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
CROLOM

>DLT>	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
>DLT>					

OPTICROM

>ADD>	AT	+	ALLERGAN	4%	N18155 001
>ADD>					OCT 03, 1984
>DLT>	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
>DLT>					[redacted]

DALTEPARIN SODIUM

INJECTABLE; INJECTION
FRAGMIN

>ADD>		+	PHARMACIA AND UPJOHN	10,000 IU/9.5ML	N20287 004
>ADD>					JAN 30, 1998

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL PRESERVATIVE FREE

>ADD>		+	BEDFORD	EQ 20MG BASE/VIAL	N50731 001
>ADD>					JAN 30, 1998

DEXAMETHASONE SODIUM PHOSPHATE

>DLT>	[redacted]				
>DLT>					
>DLT>	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
>ADD>		●		EQ 0.1MG PHOSPHATE/INH	N13413 001

ENOXAPARIN SODIUM

INJECTABLE; INJECTION
LOVENOX

>ADD>		+	RHONE POULENC RORER	40MG/0.4ML	N20164 002
>ADD>					JAN 30, 1998

ERYTHROMYCIN

OINTMENT; OPHTHALMIC

ERYTHROMYCIN

>DLT>	[redacted]	[redacted]	5.2%	[redacted]	
>DLT>				[redacted]	
>ADD>	AT	AKORN	0.5%	N64030 001	
>ADD>				JUL 18, 1996	

OINTMENT; TOPICAL

AKNE-MYCIN

>DLT>	[redacted]	[redacted]	2%	[redacted]	
>DLT>				[redacted]	
>ADD>	+	HEALTHPOINT	2%	N50584 001	
>ADD>				JAN 10, 1985	

ESTRADIOL

TABLET; ORAL

ESTRADIOL

>ADD>	AB	ENDEAVOR	0.5MG	N40138 001	
>ADD>				JAN 30, 1998	
>ADD>	AB		1MG	N40138 002	
>ADD>				JAN 30, 1998	
>ADD>	AB		2MG	N40138 003	
>ADD>				JAN 30, 1998	

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

LEVORA 0.15/30-21

>DLT>	[redacted]	[redacted]	[redacted]	[redacted]	
>DLT>				[redacted]	
>ADD>	AB	WATSON LABS	0.03MG;0.15MG	N73592 001	
>ADD>				DEC 13, 1993	

TABLET; ORAL-28

LEVORA 0.15/30-28

>DLT>	[redacted]	[redacted]	[redacted]	[redacted]	
>DLT>				[redacted]	
>ADD>	AB	WATSON LABS	0.03MG;0.15MG	N73594 001	
>ADD>				DEC 13, 1993	

ETODOLAC

CAPSULE; ORAL

ETODOLAC

>ADD>	AB	AESGEN	300MG	N74929 001	
>ADD>				JAN 30, 1998	

TABLET, EXTENDED RELEASE; ORAL

LODINE XL

>ADD>	+	WYETH AYERST	500MG	N20584 003	
>ADD>				JAN 20, 1998	

ETOPOSIDE

INJECTABLE; INJECTION

ETOPOSIDE

>ADD>	AP	MARSAM	20MG/ML	N74968 001	
>ADD>				JAN 09, 1998	

FENFLURAMINE HYDROCHLORIDE

TABLET; ORAL

[redacted]

>DLT>	[redacted]	[redacted]	[redacted]	[redacted]	
>DLT>				[redacted]	
>DLT>	[redacted]	[redacted]	20MG	[redacted]	
>ADD>	@		20MG	N16618 001	

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

>ADD>	AO	BEDFORD	EQ 50MG BASE/ML	N74811 001	
>ADD>				JAN 30, 1998	

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

>ADD>	AB	BARR	25MG;37.5MG	N74970 001	
>ADD>				JAN 06, 1998	

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S ADVIL

>DLT<	##	[redacted]	[redacted]	[redacted]	
>DLT<					
>ADD<	BX	WHITEHALL ROBINS	100MG/5ML	N19833 002 SEP 19, 1989	
>ADD<					

IPRATROPIUM BROMIDE

AEROSOL, METERED; INHALATION
ATROVENT

>DLT<		[redacted]	[redacted]	[redacted]	
>DLT<					
>ADD<	+		0.018MG/INH	N19085 001 DEC 29, 1986	
>ADD<					

ISOSULFAN BLUE

INJECTABLE; INJECTION
LYMPHAZURIN

>DLT<	#	[redacted]	1%	[redacted]	
>ADD<	+	US SURGCL	1%	N18310 001	

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL
ORUVAIL

>DLT<	#	[redacted]	[redacted]	[redacted]	
>DLT<					
>DLT<	#		[redacted]	[redacted]	
>DLT<					
>ADD<			100MG	N19816 003 FEB 08, 1995	
>ADD<					
>ADD<			150MG	N19816 002 FEB 08, 1995	
>ADD<					

MALATHION

LOTION; TOPICAL
OVIDE

>DLT<	#	[redacted]	[redacted]	[redacted]	
>DLT<					

MALATHION

LOTION; TOPICAL
OVIDE

>ADD<		@ MEDICIS	0.5%		N18613 001 AUG 02, 1982
>ADD<					

NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION; IRRIGATION
NEOSPORIN G.U. IRRIGANT

>DLT<	##	[redacted]	[redacted]	[redacted]	
>DLT<					
>ADD<	AT	MONARCH PHARMS	EQ 40MG BASE/ML; 200,000 UNITS/ML		N60707 001
>ADD<					

PERMETHRIN

CREAM; TOPICAL
ELIMITE

>ADD<	AB	+ ALLERGAN	5%		N19855 001 AUG 25, 1989
>ADD<					

PERMETHRIN

>ADD<	AB	ALPHARMA	5%		N74806 001 JAN 23, 1998
>ADD<					

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCHLORPERAZINE MALEATE

>ADD<	AB	ZENITH GOLDLINE	EQ 5MG BASE		N40162 001 JAN 20, 1998
>ADD<					
>ADD<	AB		EQ 10MG BASE		N40162 002 JAN 20, 1998
>ADD<					

RANITIDINE HYDROCHLORIDE

SYRUP; ORAL
ZANTAC

>DLT<		[redacted]	[redacted]	[redacted]	
>DLT<					
>ADD<	+		EQ 15MG BASE/ML		N19675 001 DEC 30, 1988
>ADD<					

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE HCL

>ADD>	AB	RANBAXY	EQ 150MG BASE	N75000 001	
>ADD>				JAN 30, 1998	
>ADD>	AB		EQ 300MG BASE	N75000 002	
>ADD>				JAN 30, 1998	

SOYBEAN OIL

INJECTABLE; INJECTION
INTRALIPID 30%

>ADD>	AP	+ PHARMACIA AND UPJOHN	30%	N19942 001	
>ADD>				DEC 30, 1993	
>ADD>		LIPOSYN III 30%			
>ADD>	AP	+ ABBOTT	30%	N20181 001	
>ADD>				JAN 13, 1998	

SULFASALAZINE

TABLET; ORAL
SULFASALAZINE

>DLT>	AB	[redacted]	[redacted]	[redacted]	
>DLT>				OCT 26, 1987	
>ADD>		●	500MG	N89339 001	
>ADD>				OCT 26, 1987	

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION
TECHNETIUM TC 99M ALBUMIN AGGREGATED KIT

>ADD>	BS	DRAXIMAGE	N/A	N17881 001	
>ADD>				DEC 30, 1987	
>DLT>	BS	[redacted]	[redacted]	[redacted]	
>DLT>				[redacted]	

TECHNETIUM TC-99M GLUCEPTATE KIT

INJECTABLE; INJECTION
TECHNESCAN GLUCEPTATE

>ADD>	AP	DRAXIMAGE	N/A	N18272 001	
>ADD>				JAN 27, 1982	
>DLT>	AP	[redacted]	[redacted]	[redacted]	
>DLT>				[redacted]	

TECHNETIUM TC-99M LIDOFENIN KIT

INJECTABLE; INJECTION
TECHNESCAN HIDA

>ADD>		DRAXIMAGE	N/A	N18489 001	
>ADD>				OCT 31, 1986	
>DLT>		[redacted]	[redacted]	[redacted]	
>DLT>				[redacted]	

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
TECHNESCAN MDP KIT

>ADD>	AP	DRAXIMAGE	N/A	N18035 001	
>DLT>	AP	[redacted]	[redacted]	[redacted]	

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
DTPA

>ADD>	AP	DRAXIMAGE	N/A	N18511 001	
>ADD>				DEC 29, 1989	
>DLT>	AP	[redacted]	[redacted]	[redacted]	
>DLT>				[redacted]	

TECHNETIUM TC-99M SULFUR COLLOID KIT

SOLUTION; INJECTION, ORAL

>DLT>		[redacted]			
>DLT>	AP	[redacted]	[redacted]	[redacted]	
>ADD>		●	N/A	N17858 001	

>ADD> TOLCAPONE

TABLET; ORAL
TASMAR

>ADD>		ROCHE	100MG	N20697 001	
>ADD>				JAN 29, 1998	
>ADD>		+	200MG	N20697 002	
>ADD>				JAN 29, 1998	

TRETINOIN

GEL; TOPICAL

>ADD>	AVITA			
>ADD>	PENEDERM	0.025%	N20400 001	
>ADD>			JAN 29, 1998	

>ADD< ACETAMINOPHEN; ASPIRIN; CAFFEINE

>ADD< TABLET; ORAL
>ADD< EXCEDRIN (MIGRAINE)
>ADD< + BRISTOL MYERS 250MG;250MG;65MG N20802 001
>ADD< JAN 14, 1998

IBUPROFEN

SUSPENSION/DROPS; ORAL
>ADD< PEDIATRIC ADVIL
>ADD< + WHITEHALL ROBINS 100MG/2.5ML N20812 001
>ADD< JAN 30, 1998

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 '98

NO JANUARY 1998 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 1998

Name Generic Name TN=Trade Name Approval	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing
Aldesleukin TN= Proleukin	Treatment of metastatic melanoma.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=09/10/1996 MA=01/09/1998
Carbamylglutamic acid TN=	Treatment of N-acetylglutamate synthetase deficiency.	Orphan Europe Immeuble "Le Guillaumet" 60 avenue du President Wilson 92046 Paris, France DD=01/20/1998
L-baclofen TN=	Treatment of trigeminal neuralgia.	Pharmascience, Inc. 8400 Darnley Road Montrael, Quebec Canada H4T 1M4 DD=01/06/1998
Thymalfasin TN= Zadaxin	Treatment of DiGeorge anomaly with immune defects.	SciClone Pharmaceuticals Inc. 901 Mariner's Island Blvd. San Mateo, CA 94404 DD=01/08/1998

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

NO JANUARY 1998 ADDITIONS

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, 18TH EDITION FOR A FULL LISTING OF PATENT AND 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-212	TREATMENT OF SYMPTOMS OF DRY MOUTH IN PATIENTS WITH SJOGREN'S SYNDROME
I-213	TEMPORARY RELIEF OF PAIN AND PHOTOPHOBIA IN PATIENTS UNDERGOING CORNEAL REFRACTIVE SURGERY
I-214	TREATMENT OF OSTEOPOROSIS
I-215	PRE-PROCEDURAL APPLICATION TO ADULT MALE GENITAL SKIN PRIOR TO SITE-SPECIFIC SUBCUTANEOUS INFILTRATION WITH LIDOCAINE FOR THE REMOVAL OF GENITAL WARTS
I-216	FOR THE LONG-TERM TWICE-DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD, INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA
I-217	PREVENTION (DURING AND FOLLOWING HOSPITALIZATION) OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY

PATENT USE CODE

U-215	TREATMENT OF EPILEPSY TWICE DAILY. TREATING A PATIENT BY ADMINISTERING CARBAMAZEPINE IN A DOSAGE FORM CAPABLE OF MAINTAINING BLOOD CONCENTRATION FROM 4-12MCG/ML OVER 12 HOURS
U-216	TREATMENT OF ADENOCARCINOMA, INCLUDING STAGE B2-C,BY ADMINISTERING AN AGONIST OF LR-RH AND FLUTAMIDE
U-217	METHOD OF PRODUCING ANESTHESIA
U-218	METHOD FOR LIMITING THE POTENTIAL FOR MICROBIAL GROWTH IN THE DRUG PRODUCT
U-219	TREATMENT OF PARKISON'S DISEASE

BLANK

PAGE

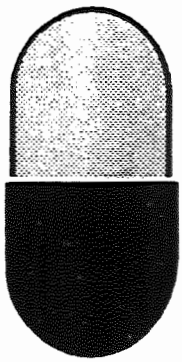
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020802	001	ACETAMINOPHEN;EXCEDRIN (MIGRAINE)				NP	JAN 14, 2001
020420	001	ARBUTAMINE HYDROCHLORIDE;GENESA	5108363	APR 28, 2009	U-220		
			5234404	AUG 10, 2010	U-220		
			5395970	MAR 07, 2012			
020114	001	AZELASTINE HYDROCHLORIDE;ASTELIN	5164194	NOV 01, 2010	U-207		
017573	001	BECLOMETHASONE DIPROPIONATE;VANCERIL	4364923	DEC 21, 1999			
018521	001	BECLOMETHASONE DIPROPIONATE;VANCENASE	4364923	DEC 21, 1999			
020486	001	BECLOMETHASONE DIPROPIONATE;VANCERIL DOUBLE STRENGTH	4364923	DEC 21, 1999			
020712	001	CARBAMAZEPINE;CARBATROL	5326570	JUL 05, 2011	U-215		
020712	002	CARBAMAZEPINE;CARBATROL	5326570	JUL 05, 2011	U-215		
020297	001	CARVEDILOL;COREG	4503067	MAR 05, 2007	U-3		
020297	002	CARVEDILOL;COREG	4503067	MAR 05, 2007	U-3		
020297	003	CARVEDILOL;COREG	4503067	MAR 05, 2007	U-3		
020805	001	CIPROFLOXACIN HYDROCHLORIDE;CIPRO HC				NC	FEB 10, 2001
020839	001	CLOPIDOGREL BISULFATE;PLAVIX	4529596	JUL 05, 2003			
			4847265	FEB 12, 2008			
			5576328	JAN 31, 2014			
020037	001	DICLOFENAC [redacted]				I-213	FEB 25, 2001
020401	001	DILTIAZEM [redacted]				I-133	JAN 30, 2001
020401	002	DILTIAZEM [redacted]				I-133	JAN 30, 2001
020401	003	DILTIAZEM [redacted]				I-133	JAN 30, 2001
020401	004	DILTIAZEM [redacted]				I-133	JAN 30, 2001
020401	005	DILTIAZEM [redacted]				I-133	JAN 30, 2001
020164	001	ENOXAPARIN [redacted]				I-217	JAN 30, 2001
020738	004	EPROSARTAN [redacted]	5185351	FEB 09, 2010	U-3		
020738	005	EPROSARTAN [redacted]	5185351	FEB 09, 2010	U-3		
083209	001	ESTROGENS, [redacted]				I-214	MAR 10, 2001
086715	001	ESTROGENS, [redacted]				I-214	MAR 10, 2001
020363	001	FANCICLOVIR;FAMVIR				NCE	JUN 29, 1999
020786	001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	4254129	APR 10, 1999			
			5375693	AUG 03, 2012			
			5578610	NOV 26, 2013			
018554	001	FLUTAMIDE;EULEXIN	4472382	SEP 18, 2001	U-24		
			5712251	SEP 18, 2001	U-216		
020818	001	HYDROCHLOROTHIAZIDE;DIOVAN HCT				NCE	DEC 23, 2001
						NC	MAR 06, 2001
020818	002	HYDROCHLOROTHIAZIDE;DIOVAN HCT				NCE	DEC 23, 2001
						NC	MAR 06, 2001
016295	001	HYDROXYUREA;HYDREA				ODE	FEB 25, 2005
020812	001	IBUPROFEN;PEDIATRIC ADVIL				NP	JUN 16, 1998
019927	001	KETOCONAZOLE;NIZORAL	4942162	FEB 11, 2003			
019732	001	LEUPROLIDE ACETATE;LUPRON DEPOT	5716640	SEP 02, 2013			
020011	001	LEUPROLIDE ACETATE;LUPRON DEPOT	5716640	SEP 02, 2013			
020517	001	LEUPROLIDE ACETATE;LUPRON DEPOT	5716640	SEP 02, 2013			
020263	002	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020263	003	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020263	004	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020263	005	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020263	006	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			

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
020708	001	LEUPROLIDE ACETATE;LUPRON DEPOT-3	5716640	SEP 02, 2013			
020517	002	LEUPROLIDE ACETATE;LUPRON DEPOT-4	5716640	SEP 02, 2013			
019941	001	LIDOCAINE;EMLA				I-215	FEB 04, 2001
020962	001	LIDOCAINE;EMLA				NP	FEB 04, 2001
020606	001	LOPERAMIDE HYDROCHLORIDE;IMODIUM ADVANCED	5716641	MAY 21, 2012			
020762	001	MOMETASONE FUROATE MONOHYDRATE;NASONEX	4472393	SEP 18, 2001			
020830	001	MONTELUKAST SODIUM;SINGULAIR				NCE	FEB 20, 2003
020829	002	MONTELUKAST SODIUM;SINGULAR				NCE	FEB 20, 2003
020763	001	NARATRIPTAN HYDROCHLORIDE;AMERGE				NCE	FEB 10, 2003
020763	002	NARATRIPTAN HYDROCHLORIDE;AMERGE				NCE	FEB 10, 2003
020237	001	PILOCARPINE HYDROCHLORIDE;SALAGEN				CDE	FEB 11, 2005
						I-212	FEB 11, 2001
019627	002	PROPOFOL;DIPRIVAN	5731355	MAR 22, 2015	U-217		
			5731356	MAR 22, 2015	U-218		
020815	001	RALOXIFENE HYDROCHLORIDE;EVISTA	4418068	APR 03, 2001			
			5393763	JUL 28, 2012	U-114		
			5457117	JUL 28, 2012	U-114		
			5478847	MAR 02, 2014	U-114		
020272	005	RISPERIDONE;RISPERDAL	5158952	OCT 27, 2009		D-37	OCT 17, 2000
020236	001	SALMETEROL XINAFOATE;SEREVENT				I-216	FEB 05, 2001
019676	001	SOMATROPIN, BIOSYNTHETIC;NUTROPIN				CDE	OCT 29, 2004
019676	002	SOMATROPIN, BIOSYNTHETIC;NUTROPIN				CDE	OCT 29, 2004
020181	001	SOYBEAN OIL;LIPOSYN III 30%				NP	JAN 13, 2001
020791	001	TESTOSTERONE;TESTODERM	4379454	FEB 17, 2001			
020697	001	TOLCAPONE;TASMAR	5236952	AUG 17, 2010		NCE	JAN 29, 2003
			5476875	DEC 19, 2012	U-219		
020697	002	TOLCAPONE;TASMAR	5236952	AUG 17, 2010		NCE	JAN 29, 2003
			5476875	DEC 19, 2012	U-219		

New 18th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

18TH EDITION

Superintendent of Documents Subscription Order Form

Order Processing Code
* 80128

Charge your order. It's easy!

☐ **Yes,** enter my subscription as follows:

_ subscriptions of **APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS**, ADP, and the monthly Cumulative Supplements, for $77.00 per year.

The total cost of my order is $_____. Price includes regular shipping and handling and is subject to change. International customers please add 25%.

For privacy protection, check the box below:

☐ Do not make my name available to other mailers.

Please choose method of payment:

☐ Check payable to Superintendent of Documents
☐ GPO Deposit Account ☐☐☐☐☐☐-☐
☐ VISA or MasterCard
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

_____
(Credit card expiration date)

Thank you for your order!

_____
(Authorizing Signature) (11/97)

_____
Company or personal name

_____
Additional address/attention line

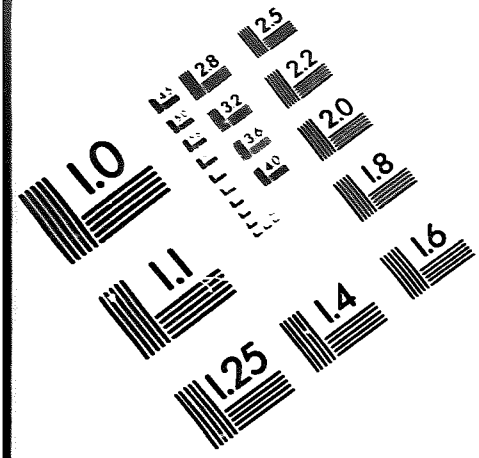
_____
Street address

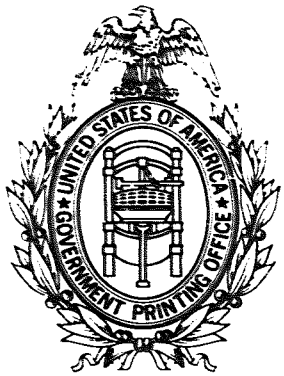
_____
City, State, ZIP Code

(_____)_____
Daytime phone including area code

_____
Purchase Order No. (optional)

Mail To: Superintendent of Documents, Government Printing Office, P.O. Box 371954 Pittsburgh, PA 15250-7954
To FAX your charge order, call (202) 512-2250.
To charge your subscription call (202) 512-1800.





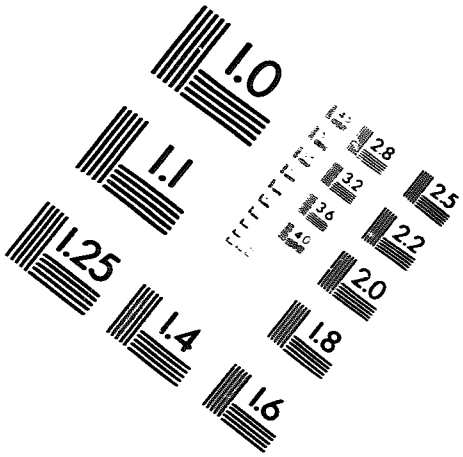
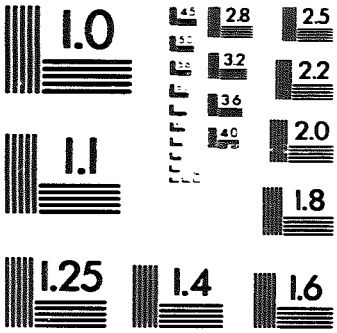
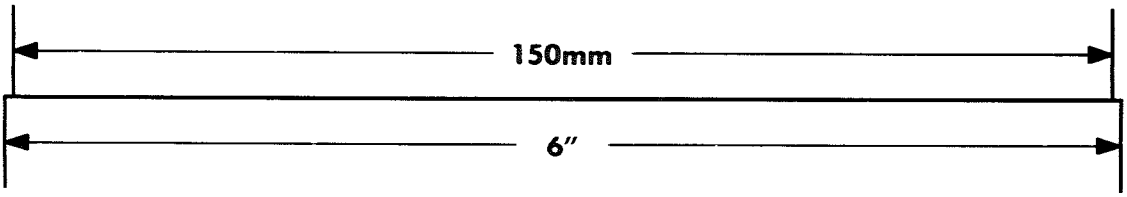
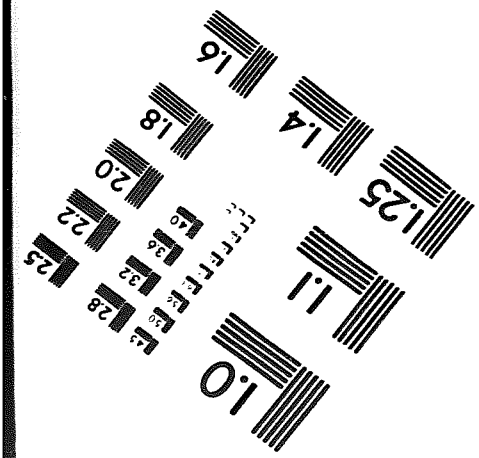


IMAGE EVALUATION
TEST TARGET QA-3







APPLIED IMAGE, Inc
1653 East Main Street
Rochester, NY 14609 USA
Phone: 716/482-0300
Fax: 716/288-5989