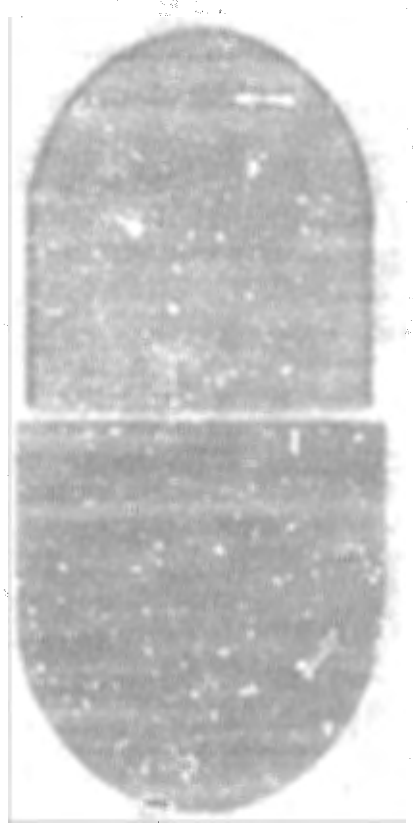

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

18TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

18TH EDITION

Cumulative Supplement 3

MARCH 1998

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

18TH EDITION

CUMULATIVE SUPPLEMENT 3
MARCH 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 - MARCH 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.

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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.

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
LIBRIUM
AB ICN 10MG N85472 001
AB + [redacted] 25MG [redacted]
[redacted]
[redacted]

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
PERIDEX
AT * [redacted] 0.12% [redacted]
AT + ZILA 0.12% N19028 001
AUG 13, 1986

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL
AB [redacted] [redacted] [redacted]
● 25MG/ML N89563 001
APR 15, 1988

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE
AA [redacted] [redacted] [redacted]
AA WATSON LABS 500MG N81040 001
AUG 22, 1989

CIPROFLOXACIN HYDROCHLORIDE

> ADD > OINTMENT; OPHTHALMIC
> ADD > CILOXAN
> ADD > + ALCON EQ 0.3% BASE N20369 001
> ADD > MAR 30, 1998

CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE

SUSPENSION/DROPS; OTIC
CIPRO HC
+ BAYER EQ 0.2% BASE;1% N20805 001
FEB 10, 1998

CLEMASTINE FUMARATE

SYRUP; ORAL
CLEMASTINE FUMARATE
> ADD > AA NORTON GROVE EQ 0.5MG BASE/5ML N74863 001
> ADD > MAR 13, 1998

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE
AB [redacted] [redacted] [redacted]
● EQ 150MG BASE/ML N62913 001
OCT 20, 1988

SOLUTION; TOPICAL
CLEOCIN T
AB [redacted] [redacted] [redacted]
● EQ 1% BASE N62363 001
FEB 08, 1982

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION
COLY-MYCIN M
* [redacted] [redacted] [redacted]
> DLT > + PARKEDALE EQ 150MG BASE/VIAL N50108 002
> ADD >

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
CROLOM
AT BAUSCH AND LOMB 4% N74443 001
* [redacted] [redacted] JAN 30, 1995
[redacted]

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
OPTICROM
AT + ALLERGAN 4% N18155 001 OCT 03, 1984
[redacted]

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL
[redacted]
AB WATSON LABS 10MG N74436 001 NOV 30, 1994

DACTINOMYCIN

INJECTABLE; INJECTION
COSMEGEN
+ MERCK 0.5MG/VIAL N50682 001
[redacted]

DALTEPARIN SODIUM

INJECTABLE; INJECTION
FRAGMIN
+ PHARMACIA AND UPJOHN 10,000 IU/9.5ML N20287 004 JAN 30, 1998

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL PRESERVATIVE FREE
+ BEDFORD EQ 20MG BASE/VIAL N50731 001 JAN 30, 1998

DEXAMETHASONE SODIUM PHOSPHATE

[redacted]
● MEDEVA EQ 0.1MG PHOSPHATE/INH N13413 001
[redacted]
● EQ 0.1MG PHOSPHATE/INH N14242 001

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM
[redacted]
● 5MG/ML N72371 001 JAN 29, 1993

DICYCLOMINE HYDROCHLORIDE

TABLET; ORAL
DICYCLOMINE HCL
[redacted]
● 20MG N84600 001 JUL 29, 1985

DIFLORASONE DIACETATE

CREAM; TOPICAL
DIFLORASONE DIACETATE
AB ALTANA 0.05% N75187 001 MAR 30, 1998
PSORCON
AB + DERMIK LABS 0.05% N20265 001 NOV 20, 1992
[redacted]

DEXAMETHASONE SODIUM PHOSPHATE

[redacted]

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HCL

> ADD >	AB2	MYLAN	120MG	N75124 002 MAR 18, 1998
> ADD >				
> ADD >	AB2		180MG	N75124 003 MAR 18, 1998
> ADD >				
> ADD >	AB2		240MG	N75121 001 MAR 18, 1998
> ADD >				
		TIAZAC		
		[redacted]	[redacted]	[redacted]
			360MG	N20401 005 SEP 11, 1995

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL

DIPHENHYDRAMINE HCL

	AA	[redacted]	[redacted]	[redacted]
		●	12.5MG/5ML	N83237 001 JAN 25, 1982

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTAMINE HCL

	AP	MARSAM	EQ 12.5MG BASE/ML	N74279 001 FEB 18, 1998
> ADD >	AP		EQ 12.5MG BASE/ML	N74995 001 MAR 31, 1998
> ADD >				

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIN HCL

	AB	[redacted]	[redacted]	[redacted]
	AB		[redacted]	[redacted]
	AB		[redacted]	[redacted]
	AB	WATSON LABS	EQ 10MG BASE	[redacted] MAR 29, 1991

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIN HCL

	AB	WATSON LABS	EQ 25MG BASE	N72986 001 MAR 29, 1991
	AB		EQ 50MG BASE	N72987 001 MAR 29, 1991

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

RUBEX

> DLT >	AP	[redacted]	[redacted]	[redacted]
> DLT >				
> DLT >	AP		[redacted]	[redacted]
> DLT >				
> DLT >			[redacted]	[redacted]
> DLT >				
> ADD >	AP	BRISTOL MYERS SQUIBB	10MG/VIAL	[redacted] APR 13, 1989
> ADD >				
> ADD >	AP		50MG/VIAL	N62926 002 APR 13, 1989
> ADD >				
> ADD >			100MG/VIAL	N62926 003 APR 13, 1989
> ADD >				

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

EDROPHONIUM CHLORIDE

	AP	ABBOTT	10MG/ML	N40131 001 FEB 24, 1998

ENCAINIDE HYDROCHLORIDE

> DLT >	[redacted]			
> DLT >				
> DLT >		[redacted]	[redacted]	[redacted]
> DLT >				
> DLT >			[redacted]	[redacted]
> DLT >				
> ADD >		●	25MG	N18981 002 DEC 24, 1986
> ADD >				
> ADD >		●	35MG	N18981 003 DEC 24, 1986
> ADD >				

ENOXAPARIN SODIUM

INJECTABLE; INJECTION
LOVENOX

	+	RHONE POULENC RORER	40MG/0.4ML	N20164 002 JAN 30, 1998	
> ADD >	+		60MG/0.6ML	N20164 003 MAR 27, 1998	
> ADD >	+		80MG/0.8ML	N20164 004 MAR 27, 1998	
> ADD >	+		100MG/ML	N20164 005 MAR 27, 1998	

ERYTHROMYCIN

OINTMENT; OPHTHALMIC
ERYTHROMYCIN

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

OINTMENT; TOPICAL
AKNE-MYCIN

	*	[redacted]	[redacted]	
	+	HEALTHPOINT	2%	N50584 001 JAN 10, 1985

TABLET, DELAYED RELEASE; ORAL
E-MYCIN

[redacted]	*	[redacted]	[redacted]	
AB		333MG	N60272 002	

ERY-TAB

[redacted]		[redacted]	[redacted]	
AB	+	250MG	N62298 001	
[redacted]		[redacted]	[redacted]	
AB	+	333MG	N62298 003 MAR 29, 1982	
[redacted]		[redacted]	[redacted]	
AB	+	500MG	N62298 002	

ESTAZOLAM

TABLET; ORAL
ESTAZOLAM

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
AB	WATSON LABS	1MG	N74818 001 AUG 19, 1997
AB		2MG	N74818 002 AUG 19, 1997

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL
CLIMARA

> ADD > BX	+	BERLEX	0.075MG/24HR	N20375 003 MAR 23, 1998

TABLET; ORAL
ESTRADIOL

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

ESTRONE

INJECTABLE; INJECTION
THELIN

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
●	PARKEDALE	1MG/ML	N03977 001
●		2MG/ML	N03977 002
●		5MG/ML	N03977 003

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21
LEVORA 0.15/30-21

[redacted]	[redacted]	[redacted]	[redacted]

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21
LEVORA 0.15/30-21
AB WATSON LABS 0.03MG;0.15MG N73592 001 DEC 13, 1993

TABLET; ORAL-28
LEVORA 0.15/30-28
[redacted]
AB WATSON LABS 0.03MG;0.15MG N73594 001 DEC 13, 1993

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/35E-21
> DLT > [redacted]
> DLT >
> ADD > AB SEARLE 0.035MG;1MG N71480 001 APR 12, 1988
> ADD >

TABLET; ORAL-28
NORETHIN 1/35E-28
> DLT > [redacted]
> DLT >
> ADD > AB SEARLE 0.035MG;1MG N71481 001 APR 12, 1988
> ADD >

ETODOLAC

CAPSULE; ORAL
ETODOLAC
AB AESGEN 300MG N74929 001 JAN 30, 1998

TABLET; ORAL
ETODOLAC
AB MYLAN 400MG N75104 001 FEB 06, 1998
[redacted]
> ADD > AB TARO 400MG N75074 001 MAR 11, 1998
> ADD >
AB WATSON LABS 400MG N74892 001 APR 16, 1997

ETODOLAC

TABLET, EXTENDED RELEASE; ORAL
LODINE XL
+ WYETH AYERST 500MG N20584 003 JAN 20, 1998

ETOPOSIDE

INJECTABLE; INJECTION
ETOPOSIDE
AP MARSAM 20MG/ML N74968 001 JAN 09, 1998

ETOPOSIDE PHOSPHATE

INJECTABLE; INJECTION
[redacted]
ETOPOPHOS PRESERVATIVE FREE
+ BRISTOL MYERS SQUIBB EQ 100MG BASE/VIAL N20457 001 MAY 17, 1996
+ EQ 500MG BASE/VIAL N20906 001 FEB 27, 1998

FENFLURAMINE HYDROCHLORIDE

[redacted]

FENOFIBRATE

CAPSULE; ORAL
LIPIDIL
@ ABBOTT 100MG N19304 001 DEC 31, 1993
[redacted]

TRICOR (MICRONIZED)
+ ABBOTT 67MG N19304 002 FEB 09, 1998

FENTANYL CITRATE

INJECTABLE; INJECTION

[redacted]					
AP		ABBOTT	[redacted]	[redacted]	> DLT >
AP	*	ELKINS SINN	[redacted]	[redacted]	> DLT >
					> ADD >
					> ADD >

FENTANYL CITRATE PRESERVATIVE FREE

AP		ABBOTT	EQ 0.05MG BASE/ML	M72786 001 SEP 24, 1991
AP	*	ELKINS SINN	EQ 0.05MG BASE/ML	M19101 001 JUL 11, 1984
AP		MARSAM	EQ 0.05MG BASE/ML	M74917 001 FEB 03, 1998
[redacted]				
AP	*	JANSSEN	EQ 0.05MG BASE/ML	[redacted]

SUBLIMAZE PRESERVATIVE FREE

AP	+	JANSSEN	EQ 0.05MG BASE/ML	M16619 001

FLOSEQUINAN

TABLET; ORAL

		[redacted]		
> DLT >		KROLL PHARM	50MG	[redacted]
> DLT >			75MG	
> DLT >			[redacted]	
> DLT >	*		[redacted]	
> DLT >				
> ADD >	●		50MG	M19960 001 DEC 30, 1992
> ADD >	●		75MG	M19960 002 DEC 30, 1992
> ADD >	●		100MG	M19960 003 DEC 30, 1992

FLUVOXAMINE MALEATE

TABLET; ORAL

LUVOX

[redacted]				
	*	[redacted]	[redacted]	[redacted]
			25MG	M20243 001 DEC 05, 1994

GEMFIBROZIL

CAPSULE; ORAL

LOPID

[redacted]				
	*	[redacted]	[redacted]	[redacted]
	●	PARKE DAVIS PHARMS	200MG	N18422 001
	●		300MG	N18422 002

TABLET; ORAL

LOPID

[redacted]				
	*	[redacted]	[redacted]	[redacted]
AB	+	PARKE DAVIS PHARMS	600MG	N18422 003 NOV 20, 1986

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

GUANFACINE HCL

[redacted]				
		[redacted]	[redacted]	[redacted]
			[redacted]	[redacted]
AB		WATSON LABS	EQ 1MG BASE	M74762 001 JUN 25, 1997
AB			EQ 2MG BASE	M74762 002 JUN 25, 1997

HALOPERIDOL

TABLET; ORAL

HALOPERIDOL

[redacted]				
		[redacted]	[redacted]	[redacted]
	●		0.5MG	M71071 001 NOV 03, 1986

HALOPERIDOL

TABLET; ORAL
HALOPERIDOL

@	PUREPAC PHARM	1MG	N71072 001 NOV 03, 1986
@		2MG	N71073 001 NOV 03, 1986
@		5MG	N71074 001 NOV 03, 1986
@		10MG	N71075 001 AUG 04, 1987
@		20MG	N71076 001 AUG 04, 1987

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE

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

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL

AP	[redacted]	[redacted]	[redacted]
AP		[redacted]	[redacted]
@		EQ 5MG BASE/ML	N72516 001 FEB 25, 1993
@		EQ 5MG BASE/ML	N72517 001 FEB 25, 1993

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	B BRAUN	200 UNITS/100ML	N19953 001 JUL 20, 1992
@		200 UNITS/100ML	N19042 001 MAR 29, 1985
AP	[redacted]	[redacted]	[redacted]

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

@	[redacted]	[redacted]	[redacted]

HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

@	B BRAUN	5,000 UNITS/100ML	N19802 001 JUL 20, 1992
@	[redacted]	[redacted]	[redacted]

HEPARIN SODIUM 2,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

@	B BRAUN	200 UNITS/100ML	N19042 002 MAR 29, 1985
@	[redacted]	[redacted]	[redacted]

HEPARIN SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	B BRAUN	4,000 UNITS/100ML	N19952 001 JUL 20, 1992
AP	[redacted]	[redacted]	[redacted]

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	B BRAUN	5,000 UNITS/100ML	N19952 004 JUL 20, 1992
AP		10,000 UNITS/100ML	N19952 005 JUL 20, 1992
@		5,000 UNITS/100ML	N19134 001 MAR 29, 1985
AP	[redacted]	[redacted]	[redacted]
AP		[redacted]	[redacted]
@		[redacted]	[redacted]

HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

@	B BRAUN	5,000 UNITS/100ML	N19802 005 JUL 20, 1992
@		10,000 UNITS/100ML	N19802 002 JUL 20, 1992
@	[redacted]	[redacted]	[redacted]
@		[redacted]	[redacted]

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

@	B BRAUN	5,000 UNITS/100ML	N19135 001 MAR 29, 1985	
@		5,000 UNITS/100ML	N19802 003 JUL 20, 1992	> ADD >
@	MCGAW	[illegible]	[illegible]	> ADD >
@		[illegible]	[illegible]	> ADD >

HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

@	B BRAUN	1,000 UNITS/100ML	N19042 004 MAR 29, 1985	> ADD >
@	MCGAW	[illegible]	[illegible]	> ADD >

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

AVAPRO HCT

@	SANOFI	12.5MG;75MG	N20758 001 SEP 30, 1997	
+		12.5MG;150MG	N20758 002 SEP 30, 1997	

IRBESARTAN-HYDROCHLOROTHIAZIDE

@	MYLAN	[illegible]	[illegible]	> ADD >
@		[illegible]	[illegible]	> ADD >

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	[illegible]	[illegible]	[illegible]	> DLT >
AB		[illegible]	[illegible]	
@		15MG;250MG	N70829 001 MAR 09, 1987	
@		25MG;250MG	N70830 001 MAR 09, 1987	

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL

DIOVAN HCT

	NOVARTIS	12.5MG;80MG	N20818 001 MAR 06, 1998	> ADD >
+		12.5MG;160MG	N20818 002 MAR 06, 1998	> ADD >

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATE

AB	[illegible]	[illegible]	[illegible] NOV 30, 1995	
AB	WATSON LABS	200MG	N40133 001 NOV 30, 1995	

HYDROXYUREA

CAPSULE; ORAL

DROXIA

	BRISTOL MYERS SQUIBB	200MG	N16295 002 FEB 25, 1998	> ADD >
		300MG	N16295 003 FEB 25, 1998	> ADD >
+		400MG	N16295 004 FEB 25, 1998	> ADD >

HYDREA

AB	+ BRISTOL MYERS SQUIBB	500MG	N16295 001	> ADD >
AB	@ MYLAN	[illegible]	[illegible]	> DLT >

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HCL

AB	[illegible]	[illegible]	[illegible]

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL

[illegible]	[illegible]	[illegible]	[illegible]		
[illegible]	[illegible]	[illegible]	[illegible]		
AB	WATSON LABS	10MG	N81149 001 MAR 18, 1994		
AB		25MG	N81150 001 MAR 18, 1994		
AB		50MG	N81151 001 MAR 18, 1994	>ADD >ADD<	

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S ADVIL

[illegible]	[illegible]	[illegible]	[illegible]		
BX	WHITEHALL ROBINS	100MG/5ML	N19833 002 SEP 19, 1989		
>ADD< >ADD< >ADD<	IBUPROFEN ALPHARMA	100MG/5ML	N74978 001 MAR 25, 1998		
>ADD< >ADD< >DLT< >DLT<	MOTRIN + MCNEIL	100MG/5ML	N19842 001 SEP 19, 1989		
[illegible]	[illegible]	[illegible]	[illegible]		

TABLET; ORAL
IBUPROFEN

[illegible]	[illegible]	[illegible]	[illegible]		
[illegible]	[illegible]	[illegible]	[illegible]		
[illegible]	[illegible]	[illegible]	[illegible]		
●		400MG	N72064 001 JAN 14, 1988		
●		600MG	N72065 001 JAN 14, 1988		
●		800MG	N71938 001 JAN 14, 1988		

INDAPAMIDE

TABLET; ORAL
INDAPAMIDE

AB	TEVA	1.25MG	N74498 002 FEB 12, 1998		

IOPAMIDOL

INJECTABLE; INJECTION
IOPAMIDOL

AP	ELKINS SINN	51%	N74629 004 MAR 31, 1998		

IOPAMIDOL-250

AP	ABBOTT	51%	N75005 001 FEB 24, 1998		

IOPAMIDOL-300

AP	ABBOTT	61%	N75005 002 FEB 24, 1998		

IOPAMIDOL-370

AP	ABBOTT	76%	N75005 003 FEB 24, 1998		

IOTROLAN

INJECTABLE; INTRATHECAL
OSMOVIST 190

[illegible]	[illegible]	[illegible]	[illegible]		
	BERLEX LABS	40.6%	N19580 001 DEC 07, 1989		

OSMOVIST 240

[illegible]	[illegible]	[illegible]	[illegible]		
	BERLEX LABS	51.3%	N19580 002 DEC 07, 1989		

IPRATROPIUM BROMIDE

AEROSOL, METERED; INHALATION
ATROVENT

[illegible]	[illegible]	[illegible]	[illegible]		
+		0.018MG/INH	N19085 001 DEC 29, 1986		

ISOSULFAN BLUE

INJECTABLE; INJECTION
LYMPHAZURIN

	*	[redacted]	[redacted]	[redacted]
	+	US SURGCL	1%	N18310 001

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
KETALAR

> DLT >	AP	* PARKE DAVIS	[redacted]	[redacted]
> DLT >	AP	*		[redacted]
> DLT >		*		[redacted]
> ADD >	AP	+ PARKEDALE		N16812 002
> ADD >	AP	+		N16812 003
> ADD >		+		N16812 001

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL
ORUVAIL

	*	WYETH AYERST	100MG	[redacted]
	*		[redacted]	[redacted]
			100MG	N19816 003 FEB 08, 1995
			150MG	N19816 002 FEB 08, 1995

> ADD > **LEPIRUDIN**

> ADD > INJECTABLE; INJECTION
> ADD > REFLUDAN
> ADD > + HOECHST MARION ROUSS 50MG/VIAL N20807 001
> ADD > MAR 06, 1998

LIDOCAINE; PRILOCAINE

DISC; TOPICAL
EMLA

	+	ASTRA	2.5%;2.5%	N20962 001 FEB 04, 1998

LORAZEPAM

TABLET; ORAL
LORAZEPAM

	AB	[redacted]	[redacted]	[redacted]
	AB		[redacted]	
	AB		[redacted]	
	AB	WATSON LABS	0.5MG	OCT 31, 1991 N72927 001
	AB		1MG	OCT 31, 1991 N72928 001
	AB		2MG	OCT 31, 1991

> ADD > **LOTEPREDNOL ETABONATE**

> ADD > SUSPENSION/DROPS; OPHTHALMIC
> ADD > ALREX

> ADD >	+	PHARMOS	0.2%	N20803 001 MAR 09, 1998

> ADD > LOTEMAX

> ADD >	+	PHARMOS	0.5%	N20583 001 MAR 09, 1998
> ADD >	+		0.5%	N20841 001 MAR 09, 1998

MAFENIDE ACETATE

CREAM; TOPICAL
SULFAMYLON

> ADD >	+	BERTEK PHARMS	EQ 85MG BASE/GM	N16763 001
> DLT >	*	[redacted]	[redacted]	[redacted]

MALATHION

LOTION; TOPICAL
OVIDE

	*	[redacted]	0.5%	[redacted]
		@ MEDICIS	0.5%	N18613 001 AUG 02, 1982

MECAMYLAMINE HYDROCHLORIDE

TABLET; ORAL
INVERSINE

>ADD>		+ LAYTON	2.5MG		N10251 001
>DLT>		[redacted]	[redacted]		[redacted]

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE

AB		PHARMACHEMIE	40MG	N74745 001 FEB 27, 1998

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL

[redacted]		[redacted]	[redacted]	[redacted]
AA		WATSON LABS	50MG	N40186 001 JUN 30, 1997

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/50M-21

>DLT>	[redacted]	[redacted]	[redacted]	[redacted]
>DLT>				
>ADD>	AB	SEARLE	0.05MG;1MG	N71539 001 APR 12, 1988
>ADD>				

TABLET; ORAL-28
NORETHIN 1/50M-28

>DLT>	[redacted]	[redacted]	[redacted]	[redacted]
>DLT>				
>ADD>	AB	SEARLE	0.05MG;1MG	N71540 001 APR 12, 1988
>ADD>				

METHADONE HYDROCHLORIDE

TABLET, DISPERSIBLE; ORAL
METHADONE HCL

>ADD>	AA	ECR	40MG	N75082 001 MAR 25, 1998
>ADD>				

METHOCARBAMOL

INJECTABLE; INJECTION

[redacted]		[redacted]	[redacted]	[redacted]
		●	100MG/ML	N89849 001 DEC 27, 1991

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

[redacted]		[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]
		●	EQ 5MG BASE	N72436 001 JUN 22, 1989
		●	EQ 10MG BASE	N70850 001 FEB 03, 1987

MONTELUKAST SODIUM

TABLET; ORAL
SINGULAR

		+ MERCK	EQ 10MG BASE	N20829 002 FEB 20, 1998

TABLET, CHEWABLE; ORAL
SINGULAIR

		+ MERCK	EQ 5MG BASE	N20830 001 FEB 20, 1998

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

>ADD>	AP	KING PHARMS	10MG/ML	N74471 001 MAR 19, 1998
>ADD>				
>ADD>	AP		20MG/ML	N74471 002 MAR 19, 1998
>ADD>				

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
PENTAZOCINE AND NALOXONE HYDROCHLORIDES

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
AB	WATSON LABS	EQ 0.5MG BASE; EQ 50MG BASE	N74736 001 JAN 21, 1997		

NAPROXEN

TABLET, DELAYED RELEASE; ORAL

	EC-NAPROSYN				
AB	+ SYNTEX	375MG	N20067 002 OCT 14, 1994	> ADD >	
AB	+	500MG	N20067 003 OCT 14, 1994	> ADD >	
	NAPROXEN				
AB	INVAMED	375MG	N75061 001 FEB 18, 1998	> ADD >	
AB		500MG	N75061 002 FEB 18, 1998	> ADD >	
AB	PUREPAC PHARM	375MG	N74936 001 FEB 24, 1998	> ADD >	
AB		500MG	N74936 002 FEB 24, 1998		

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM

AB	AL HIKMA	EQ 250MG BASE	N74480 002 FEB 18, 1998	

NARATRIPTAN HYDROCHLORIDE

TABLET; ORAL
AMERGE

	GLAXO WELLCOME	EQ 1MG BASE	N20763 002 FEB 10, 1998	
	+	EQ 2.5MG BASE	N20763 001 FEB 10, 1998	

NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION; IRRIGATION
NEOSPORIN G.U. IRRIGANT

[redacted]	[redacted]	[redacted]	[redacted]	
AT	MONARCH PHARMS	EQ 40MG BASE/ML; 200,000 UNITS/ML	N60707 001	

NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; TYROSINE

SUSPENSION; ORAL
TPN SUSPENSION

	+ INTL MINERALS	15MG/5ML;3.75MG/5ML; 600MG/5ML	N08378 003	

NICARDIPINE HYDROCHLORIDE

CAPSULE; ORAL
NICARDIPINE HCL

AB	GENPHARM	20MG	N74928 001 MAR 19, 1998	
AB		30MG	N74928 002 MAR 19, 1998	

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL
MINITRAN

[redacted]	[redacted]	[redacted]	[redacted]	
AB1		0.1MG/HR	N19771 001 AUG 30, 1996	
[redacted]	[redacted]	[redacted]	[redacted]	
AB1		0.2MG/HR	N19772 001 AUG 30, 1996	
[redacted]	[redacted]	[redacted]	[redacted]	
AB1		0.4MG/HR	N19773 001 AUG 30, 1996	
[redacted]	[redacted]	[redacted]	[redacted]	
AB1		0.6MG/HR	N19774 001 AUG 30, 1996	

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

NITRO-DUR

[redacted]						
AB1	+	0.1MG/HR	N20145 001			APR 04, 1995
[redacted]						
AB1	+	0.2MG/HR	N20145 002			APR 04, 1995
[redacted]						
AB1	+	0.4MG/HR	N20145 004			APR 04, 1995
[redacted]						
AB1	+	0.6MG/HR	N20145 005			APR 04, 1995

NITROGLYCERIN

AB2		MYLAN	0.1MG/HR	N75033 001		FEB 06, 1998
[redacted]						
AB2			0.2MG/HR	N74609 001		AUG 30, 1996
[redacted]						
AB2			0.4MG/HR	N74607 001		AUG 30, 1996
[redacted]						
AB2			0.6MG/HR	N74559 001		AUG 30, 1996

TRANSDERM-NITRO

AB2	+	NOVARTIS	0.1MG/HR	N20144 001		FEB 27, 1996
[redacted]						
AB2	+		0.2MG/HR	N20144 002		FEB 27, 1996
[redacted]						
AB2	+		0.4MG/HR	N20144 003		FEB 27, 1996
[redacted]						

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

TRANSDERM-NITRO

AB2	+	NOVARTIS	0.6MG/HR	N20144 004		FEB 27, 1996
[redacted]						

NORETHINDRONE

TABLET; ORAL

NOR-QD

[redacted]						
	+	WATSON LABS	0.35MG	N17060 001		

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

PRILOSEC

	+	ASTRA MERCK	40MG	N19810 002	> ADD >	JAN 15, 1998

OXYBUTYNIN CHLORIDE

SYRUP; ORAL

DITROPAN

AA	+	ALZA	5MG/5ML	N18211 001		
[redacted]						

PERMETHRIN

CREAM; TOPICAL

ELIMITE

AB	+	ALLERGAN	5%	N19855 001		AUG 25, 1989

PERMETHRIN

AB		ALPHARMA	5%	N74806 001		JAN 23, 1998

PHENAZOPYRIDINE HYDROCHLORIDE; SULFISOXAZOLE

[redacted]

PHENTOLAMINE MESYLATE

INJECTABLE; INJECTION
PHENTOLAMINE MESYLATE

> ADD >	AP	BEDFORD	5MG/VIAL	N40235 001 MAR 11, 1998

REGITINE

> ADD >	AP	+ NOVARTIS	5MG/VIAL	N08278 003

PINDOLOL

TABLET; ORAL
PINDOLOL

[redacted]

		●	5MG	N74125 001 APR 28, 1993
		●	10MG	N74125 002 APR 28, 1993

[redacted]

	AB	WATSON LABS	5MG	N74437 001 FEB 27, 1995
	AB		10MG	N74437 002 FEB 27, 1995

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION
ZOSYN IN PLASTIC CONTAINER

		+ LEDERLE	EQ 40MG BASE/ML; EQ 5MG BASE/ML	N50750 001 FEB 24, 1998

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION
ZOSYN IN PLASTIC CONTAINER

		+ LEDERLE	EQ 4GM BASE/100ML; EQ 500MG BASE/100ML	N50750 003 FEB 24, 1998
		+	EQ 60MG BASE/ML; EQ 7.5MG BASE/ML	N50750 002 FEB 24, 1998

PIROXICAM

CAPSULE; ORAL
PIROXICAM

[redacted]

	AB	WATSON LABS	10MG	N74460 001 SEP 29, 1995
	AB		20MG	N74460 002 SEP 29, 1995

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

[redacted]

		●	236GM/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT	N73098 001 AUG 31, 1993

POLYMYXIN B SULFATE

INJECTABLE; INJECTION

[redacted]

		●	EQ 500,000 U BASE/VIAL	N62036 001

POLYMYXIN B SULFATE

[redacted]

	AP	+	EQ 500,000 U BASE/VIAL	N60716 001

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL
MIRAPEX
PHARMACIA AND UPJOHN 0.5MG N20867 006
FEB 12, 1998

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE
[redacted]
RX + 5MG N80354 001
[redacted]
● 5MG N80339 001

PRIMIDONE

SUSPENSION; ORAL
MYSOLINE
> ADD > + ELAN PHARMA 250MG/5ML N10401 001
> DLT > [redacted]

TABLET; ORAL
MYSOLINE
> ADD > AB + ELAN PHARMA 250MG N09170 002
> ADD > + 50MG N09170 003
> DLT > [redacted]
> DLT > [redacted]

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL
[redacted]
● 500MG N89284 001
JUN 23, 1986

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE
[redacted]

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE
● MARSAM EQ 5MG BASE/ML N89675 001
DEC 05, 1988

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCHLORPERAZINE MALEATE
AB TRIGEN EQ 5MG BASE N40260 001
FEB 27, 1998
AB EQ 10MG BASE N40260 002
FEB 27, 1998
AB ZENITH GOLDLINE EQ 5MG BASE N40162 001
JAN 20, 1998
AB EQ 10MG BASE N40162 002
JAN 20, 1998

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL
[redacted]
● 25MG/ML N89463 001
MAY 02, 1988
● 50MG/ML N89477 001
MAY 02, 1988

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL
[redacted]
● 65MG N83278 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL
[redacted]

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]		
	10MG	[redacted] JUL 05, 1988		
	20MG	N71687 001 JUL 05, 1988		
	40MG	N71688 001 JUL 05, 1988		
	60MG	N72197 001 JUL 05, 1988		
	80MG	N71689 001 JUL 05, 1988		
	90MG	N72198 001 JUL 05, 1988		

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

AB	[redacted]	[redacted]	[redacted]	
	200MG	N84003 001		

RANITIDINE HYDROCHLORIDE

SYRUP; ORAL
ZANTAC

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

TABLET; ORAL
RANITIDINE HCL

AB	RANBAXY	EQ 150MG BASE	N75000 001 JAN 30, 1998	

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE HCL

AB	RANBAXY	EQ 300MG BASE	N75000 002 JAN 30, 1998	

RISEDRONATE SODIUM

TABLET; ORAL
ACTONEL

> ADD >	+ PROCTER AND GAMBLE	30MG	N20835 001 MAR 27, 1998	

SAQUINAVIR

CAPSULE; ORAL
FORTOVASE

[redacted]	[redacted]	[redacted]	[redacted]	
	+	200MG	N20828 001 NOV 07, 1997	

SILDENAFIL CITRATE

TABLET; ORAL
VIAGRA

	PFIZER	25MG	N20895 001 MAR 27, 1998	
		50MG	N20895 002 MAR 27, 1998	
	+	100MG	N20895 003 MAR 27, 1998	

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
KAYEXALATE

[redacted]	[redacted]	[redacted]	[redacted]	
AA	+	453.6GM/BOT	N11287 001	
	KIONEX			
AA	PADDOCK	454GM/BOT	N40029 001 FEB 06, 1998	

SOTALOL HYDROCHLORIDE

TABLET; ORAL

BETAPACE

> DLT >		[redacted]	[redacted]	
> DLT >				
> ADD >		120MG	N19865 005	
> ADD >			APR 20, 1994	

SOYBEAN OIL

INJECTABLE; INJECTION

INTRALIPID 30%

AP	+ PHARMACIA AND UPJOHN	30%	N19942 001	
			DEC 30, 1993	

LIPOSYN III 30%

AP	+ ABBOTT	30%	N20181 001	
			JAN 13, 1998	

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

SUCOSTRIN

AP	[redacted]	[redacted]	[redacted]	
	●	20MG/ML	N08847 001	

SUFENTANIL CITRATE

INJECTABLE; INJECTION

SUFENTA

> ADD >	AP + ARORN	EQ 0.05MG BASE/ML	N19050 001	> DLT >
> ADD >			MAY 04, 1984	> DLT >
> DLT >	[redacted]	[redacted]	[redacted]	> DLT >
> DLT >				> DLT >
				> DLT >
				> DLT >
				> DLT >
				> ADD >
				> ADD >
				> ADD >
				> ADD >
				> ADD >
				> ADD >
				> ADD >
				> ADD >

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

[redacted]

AB	TEVA	[redacted]	[redacted]	
			[redacted]	

[redacted] PEDIATRIC

AB	TEVA	[redacted]	[redacted]	
			[redacted]	

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	TEVA	200MG/5ML;40MG/5ML	N18812 001	
			JAN 28, 1983	
AB		200MG/5ML;40MG/5ML	N18812 002	
			JUN 10, 1983	

TABLET; ORAL

[redacted]

AB	TEVA	[redacted]	[redacted]	
AB		[redacted]	[redacted]	

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	TEVA	400MG;80MG	N18242 001	
AB		800MG;160MG	N18242 002	

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

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

TACRINE HYDROCHLORIDE

CAPSULE; ORAL

COGNEX

	[redacted]	[redacted]	[redacted]	
		[redacted]		
		[redacted]		
	※	[redacted]		
> ADD >	PARKE DAVIS PHARMS	EQ 10MG BASE	N20070 001	
> ADD >			SEP 09, 1993	
> ADD >		EQ 20MG BASE	N20070 002	
> ADD >			SEP 09, 1993	
> ADD >		EQ 30MG BASE	N20070 003	
> ADD >			SEP 09, 1993	
> ADD >	+	EQ 40MG BASE	N20070 004	
> ADD >			SEP 09, 1993	

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION
TECHNETIUM TC 99M ALBUMIN AGGREGATED KIT

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

TECHNETIUM TC-99M GLUCEPTATE KIT

INJECTABLE; INJECTION
TECHNESCAN GLUCEPTATE

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

TECHNETIUM TC-99M LIDOFENIN KIT

INJECTABLE; INJECTION
TECHNESCAN HIDA

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

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
TECHNESCAN MDP KIT

AP	DRAXIMAGE	N/A	N18035 001
AP	[redacted]	N/A	[redacted]

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
DTPA

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

TECHNETIUM TC-99M SULFUR COLLOID KIT

SOLUTION; INJECTION, ORAL
[redacted]

RX	[redacted]	N/A	[redacted]
	●	N/A	N17858 001

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
HYTRIN

> ADD >	AB	ABBOTT	EQ 1MG BASE	N20347 001 DEC 14, 1994
> ADD >	AB	+	EQ 2MG BASE	N20347 002 DEC 14, 1994
> ADD >	AB		EQ 5MG BASE	N20347 003 DEC 14, 1994
> ADD >	AB		EQ 10MG BASE	N20347 004 DEC 14, 1994

TERAZOSIN HCL

> ADD >	AB	GENEVA PHARMS	EQ 1MG BASE	N74823 001 MAR 30, 1998
> ADD >	AB		EQ 2MG BASE	N74823 002 MAR 30, 1998
> ADD >	AB		EQ 5MG BASE	N74823 003 MAR 30, 1998
> ADD >	AB		EQ 10MG BASE	N74823 004 MAR 30, 1998

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM

RX	[redacted]	[redacted]	[redacted]	[redacted]
	+		2.5MG/24HR	N20489 001 SEP 29, 1995

THEOPHYLLINE

[redacted]
ELIXOPHYLLIN

RX	[redacted]	[redacted]	[redacted]	[redacted]
RX	[redacted]	[redacted]	[redacted]	[redacted]

THEOPHYLLINE

[redacted]

● FOREST LABS 100MG N85545 001 JUL 31, 1984

● 200MG N83921 001 JUL 31, 1984

CAPSULE, EXTENDED RELEASE; ORAL

[redacted]

[redacted] FOREST LABS [redacted] [redacted]

[redacted]

● 125MG N86826 001 JAN 29, 1985

● 250MG N86826 002 JAN 29, 1985

THIANYLAL SODIUM

> DLT > [redacted]
> DLT > [redacted]
> DLT > [redacted] PARKE DAVIS [redacted]
> DLT > [redacted]
> DLT > [redacted]
> ADD > ● PARKEDALE 1GM/VIAL N07600 003
> ADD > ● 5GM/VIAL N07600 005
> ADD > ● 10GM/VIAL N07600 009

TOLCAPONE

TABLET; ORAL
TASMAR
ROCHE 100MG N20697 001 JAN 29, 1998

\+ 200MG N20697 002 JAN 29, 1998

> ADD > TOLTERODINE TARTRATE

> ADD > TABLET; ORAL
> ADD > DETROL
> ADD > PHARMACIA AND UPJOHN 1MG N20771 001 MAR 25, 1998
> ADD >

> ADD > TOLTERODINE TARTRATE

> ADD > TABLET; ORAL
> ADD > DETROL
> ADD > \+ PHARMACIA AND UPJOHN 2MG N20771 002 MAR 25, 1998
> ADD >

TRETINOIN

GEL; TOPICAL
AVITA
PENEDERM 0.025% N20406 001 JAN 29, 1998

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL
TRIHEXYPHENIDYL HCL
AA CIRCA 2MG N40184 001 FEB 06, 1998

AA 5MG I 40184 002 FEB 06, 1998

TROGLITAZONE

TABLET; ORAL
REZULIN
> DLT > [redacted] [redacted] [redacted]
> DLT > [redacted]
> DLT > [redacted]
> DLT > [redacted]
> DLT > [redacted]
> DLT > [redacted]
> ADD > AR PARKE DAVIS PHARMS 200MG N20720 001 JAN 29, 1997
> ADD > [redacted]
> ADD > AR 300MG N20720 003 AUG 04, 1997
> ADD > [redacted]
> ADD > AR 400MG N20720 002 JAN 29, 1997
> ADD > [redacted]

UROFOLLITROPIN

INJECTABLE; INTRAMUSCULAR
FERTINEX
\+ SERONO 75 IU/AMP N19415 002 SEP 18, 1986

UROFOLLITROPIN

INJECTABLE; INTRAMUSCULAR

	PERTINEX		
+	SERONO	150 IU/AMP	N19415 003 SEP 18, 1986
[redacted]			
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

	VERAPAMIL HCL		
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
	●	2.5MG/ML	N72233 001 FEB 26, 1993
	●	2.5MG/ML	N73485 001 SEP 27, 1993

VIDARABINE

INJECTABLE; INJECTION

	VIRA-A		
	[redacted]	[redacted]	[redacted]
	● PARKEDALE	EQ 187.4MG BASE/ML	N50523 001

OINTMENT; OPHTHALMIC

	VIRA-A		
>DLT>	[redacted]	[redacted]	[redacted]
>ADD>	+ PARKEDALE	3%	N50486 001

ACETAMINOPHEN; ASPIRIN; CAFFEINE

TABLET; ORAL
EXCEDRIN (MIGRAINE)
\+ BRISTOL MYERS — 250MG;250MG;65MG — N20802 001 JAN 14, 1998

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL
GAVISCON
> DLT > # [redacted] — [redacted] — [redacted]
> DLT > [redacted]
> ADD > — 80MG;20MG — N18685 001 DEC 09, 1983
> ADD > + — 160MG;40MG — N18685 002 DEC 09, 1983
GAVISCON-2
> DLT > # [redacted] — [redacted] — [redacted]
> DLT > [redacted]

CLOTRIMAZOLE

TABLET; VAGINAL
GYNIX
COPLEY PHARM — 100MG — N73249 001 FEB 13, 1998

IBUPROFEN

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

MICONAZOLE NITRATE

CREAM; VAGINAL
> ADD > MONISTAT 3
> ADD > + ADVANCED CARE PRODS — 4% — N20827 001 MAR 30, 1998
> ADD >

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
NICOTROL
[redacted] — [redacted] — [redacted]
[redacted]
\+ PHARMACIA AND UPJOHN — 15MG/16HR — N20536 001 JUL 03, 1996

RANITIDINE HYDROCHLORIDE

TABLET, EFFERVESCENT; ORAL
ZANTAC 75
\+ GLAXO WELLCOME — EQ 75MG BASE — N20745 001 FEB 26, 1998

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

CUMULATIVE SUPPLEMENT NUMBER 3 MARCH '98

NO MARCH 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 through March 1998

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
9-cis-retinoic acid TN=	For the topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	Ligand Pharmaceuticals Inc. 10275 Science Center Drive San Diego, CA 92121 DD=03/24/1998
Aldesleukin TN= Proleukin	Treatment of metastatic melanoma.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=09/10/1996 MA=01/09/1998
Arsenic trioxide TN=	Treatment of acute promyelocytic leukemia.	PolaRx, Inc. 787 7th Ave., 48th Floor New York, NY 10019 DD=03/03/1998
Beclomethasone dipropionate TN=	For oral administration in the treatment of intestinal graft-versus-host disease.	George B. McDonald, M.D. Fred Hutchinson Cancer Research Center 1100 Fairview Avenue North (SC-113); PO Box 19024 Seattle, WA 98109 DD=03/27/1998
Bindarit TN=	Treatment of lupus nephritis.	Angelini Pharmaceuticals, Inc. 70 Grand Avenue River Edge, NJ 07661 DD=02/03/1998

Orphan Product Designations and Approvals List
January 1998 through March 1998

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Carbamylglutamic acid TN=	Treatment of N-acetylglutanate synthetase deficiency.	Orphan Europe Immeuble "Le Guillaumet" 60 avenue du President Wilson 92046 Paris France DD=01/20/1998
Hydroxyurea TN= Droxia	Treatment of patients with sickle cell anemia as shown by the presence of hemoglobin S.	Bristol-Myers Squibb Pharmaceutical Research Institute P.O. Box 4000 Princeton, NJ 08543 DD=10/01/1990 MA=02/25/1998
L-baclofen TN=	Treatment of trigeminal neuralgia.	Pharmascience, Inc. 8400 Darnley Road Montreal, Quebec Canada H4T 1M4 DD=01/06/1998
Lepirudin TN= Refluden	Treatment of heparin-associated thrombocytopenia type II.	Hoechst Marion Roussel Frankfurt am Main Germany DD=02/13/1997 MA=03/06/1998
Pentostatin TN=	Treatment of cutaneous T-cell lymphoma.	SuperGen, Inc. Two Annbel Lane, Suite 220 San Ramon, CA 94583 DD=03/27/1998
Phenylacetate TN=	For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.	Targon Corporation 307 College Road East Princeton, NJ 08540 DD=03/06/1998
Pilocarpine HCl TN= Salagen	Treatment of xerostomia and keratoconjunctivitis sicca in Sjogren's syndrome patients.	MGI Pharma, Inc. 9900 Bren Road East Suite 300E Minneapolis, MN 55343 DD=02/28/1992 MA=02/11/1998

Orphan Product Designations and Approvals List
January 1998 through March 1998

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Recombinant humanized monclonal antibody 5c8 TN=	Treatment of immune thrombocytopenic purpura.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=02/03/1998
Recombinant humanized monoclonal antibody 5c8 TN=	Treatment of systemic lupus erythematosus.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=02/18/1998
Rifaximin TN= Normix	Treatment of hepatic encephalopathy.	Salix Pharmaceuticals, Inc. 3600 W. Bayshore Road Palo Alto, CA 94303 DD=02/10/1998
Thalidomide TN=	Treatment of primary brain malignancies.	EntreMed, Inc. 9610 Medical Center Drive, Suite 200 Rockville, MD 20850 DD=02/27/1998
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
Transgenic human alpha 1 antitrypsin TN=	Treatment of cystic fibrosis.	PPL Therapeutics (Scotland) Limited Roslin, Edinburgh EH25 9PP Scotland U.K. DD=03/06/1998

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

NO MARCH 1998 ADDITIONS

PATENT AND EXCLUSIVITY TERMS 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 DOSING *SCHEDULE*

D-38	CONTINUOUS INFUSION AS AN ALTERNATE METHOD OF ADMINISTRATION
D-39	CHANGE IN TIME TO TAKE THE DRUG PRIOR TO A MEAL TO PREVENT MEAL-INDUCED HEARTBURN SYMPTOMS FROM " ...1/2-1 HOUR BEFORE EATING..." TO "...RIGHT BEFORE EATING OR UP TO 60 MIN BEFORE CONSUMING..."
D-40	ONCE-A-DAY DOSING REGIMEN

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
I-218	
I-219	
I-220	TREATMENT OF EPISODIC HEARTBURN, ACID INDIGESTION AND SOUR STOMACH
I-221	TREATMENT OF BENIGN PROSTATIC HYPERPLASIA (BPH) IN MEN WITH AN ENLARGED PROSTATE TO IMPROVE SYMPTOMS, REDUCE THE RISK OF ACUTE URINARY RETENTION AND REDUCE THE RISK OF THE NEED OF SURGERY
I-222	PREVENTION OF ISCHEMIC COMPLICATIONS OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION, WHEN CONCURRENTLY ADMINISTERED WITH ASPIRIN
I-223	USE IN THE SYMPTOMATIC RELIEF OF RHINORRHEA ASSOICATED WITH ALLERGIC AND NONALLERGIC PERENNIAL RHINITIS IN CHILDREN AGE 6-11 YEARS
I-224	FOR THE USE IN PEDIATRIC PATIENTS 4 TO 11 YEARS OF AGE FOR THE MANAGEMENT OF THE NASAL SYMPTOMS OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS
I-225	USE IN PATIENTS WITH PREVIOUS MI AND NORMAL CHOLESTEROL LEVELS, TO REDUCE RISK OF RECURRENT MI, MYOCARDIAL REVASCULARIZATION, AND CEREBROVASCULAR DISEASE EVENTS
I-226	FIRST-LINE THERAPY FOR THE TREATMENT OF ADVANCED CARCINOMA OF THE OVARY IN COMBINATION WITH CISPLATIN
I-227	SHORT-TERM TREATMENT OF SYMPTOMATIC GASTROESOPHAGEAL REFLUX DISEASE (GERD)

PATENT AND EXCLUSIVITY TERMS

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
U-220	METHOD OF DIAGNOSIS
U-221	SELECTIVE VASODILATION BY CONTINUOUS ADENOSINE INFUSION
U-222	METHOD OF TREATING PAGETS DISEASE USING ACTONEL
U-223	TREATMENT OF BACTERIAL CONJUNCTIVITIS CAUSED BY SUSCEPTIBLE STRAINS OF MICROORGANISMS
U-224	CONTROLLING INTRAOCULAR PRESSURE
U-225	METHOD FOR DELIVERY
U-226	METHOD OF ENHANCING THE DISSOLUTION PROFILE OF A PHARMACEUTICAL FROM A SOLID DOSAGE FORM CONTAINING THE PHARMACEUTICAL AND SIMETHICONE
U-227	NASAL ADMINISTRATION

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
>ADD>	020059	001	ADENOSINE;ADENOSCAN	5070877	DEC 10, 2008	U-116		
>ADD>				5731296	MAR 24, 2015	U-221		
	019787	001	AMLODIPINE BESYLATE;NORVASC	4572909	JUL 31, 2006			
	019787	002	AMLODIPINE BESYLATE;NORVASC	4572909	JUL 31, 2006			
	019787	003	AMLODIPINE BESYLATE;NORVASC	4572909	JUL 31, 2006			
	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			
>ADD>	020816	001	BRINZOLAMIDE;AZOPT	5240923	AUG 31, 2010	U-224	NCE	APR 01, 2003
>ADD>				5378703	AUG 31, 2010	U-224		
>ADD>				5461081	OCT 24, 2012	U-225		
>ADD>	020313	002	CALCITONIN, SALMON;MIACALCIN	5733569	MAR 31, 2015	U-227		
>ADD>	020896	001	CAPECITABINE;XELODA				NCE	APR 30, 2003
>ADD>	020896	002	CAPECITABINE;XELODA				NCE	APR 30, 2003
	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		
>ADD>	020774	001	CHLORHEXIDINE GLUCONATE;PERIO CHIP				NP	MAY 15, 2001
>ADD>	020369	001	CIPROFLOXACIN HYDROCHLORIDE;CILOXAN	4670444	JUN 02, 2004	U-223	NDF	MAR 30, 2001
>ADD>	020805	001	CIPROFLOXACIN HYDROCHLORIDE;CIPRO HC	4670444	DEC 09, 2003		NC	FEB 10, 2001
>ADD>				4844902	FEB 11, 2008			
>ADD>	020780	001	CIPROFLOXACIN;CIPRO	4670444	DEC 09, 2003			
>ADD>	020780	002	CIPROFLOXACIN;CIPRO	4670444	DEC 09, 2003			
	020839	001	CLOPIDOGREL BISULFATE;PLAVIX	4529596	JUL 05, 2003			
				4847265	FEB 12, 2008			
				5576328	JAN 31, 2014			
>ADD>	019955	001	DESMOPRESSIN ACETATE;DDAVP				I-40	MAR 25, 2001
>ADD>	019955	002	DESMOPRESSIN ACETATE;DDAVP				I-40	MAR 25, 2001
>ADD>	020713	001	DESOGESTREL;MIRCETTE				NP	APR 22, 2001
	020037	001	DICLOFENAC SODIUM;VOLTAREN				I-213	FEB 25, 2001
	020401	001	DILTIAZEM HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020401	002	DILTIAZEM HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020401	003	DILTIAZEM HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020401	004	DILTIAZEM HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020401	005	DILTIAZEM HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020869	001	DORZOLAMIDE HYDROCHLORIDE;COSOPT				NC	APR 07, 2001
	020164	001	ENOXAPARIN SODIUM;LOVENOX				I-217	JAN 30, 2001
							I-222	MAR 27, 2001
	020164	002	ENOXAPARIN SODIUM;LOVENOX				I-222	MAR 27, 2001
>ADD>							I-217	JAN 30, 2001
	020738	004	EPROSARTAN MESYLATE;TEVETEN	5185351	FEB 09, 2010	U-3		
	020738	005	EPROSARTAN MESYLATE;TEVETEN	5185351	FEB 09, 2010	U-3		

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>	020718	001	EPTIFIBATIDE;INTEGRILIN				NCE	MAY 18, 2003
>ADD>	020718	002	EPTIFIBATIDE;INTEGRILIN				NCE	MAY 18, 2003
>ADD>	020375	003	ESTRADIOL;CLIMARA	5223261	JUN 29, 2010			
	083209	001	ESTROGENS, ESTERIFIED;ESTRATAB				I-214	MAR 10, 2001
	086715	001	ESTROGENS, ESTERIFIED;ESTRATAB				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			
	020180	001	FINASTERIDE;PROSCAR				I-221	MAR 20, 2001
>ADD>	018830	001	FLECAINIDE ACETATE;TAMBOCOR	4642384	FEB 10, 2004			
>ADD>	018830	002	FLECAINIDE ACETATE;TAMBOCOR	4642384	FEB 10, 2004			
>ADD>	018830	003	FLECAINIDE ACETATE;TAMBOCOR	4642384	FEB 10, 2004			
>ADD>	018830	004	FLECAINIDE ACETATE;TAMBOCOR	4642384	FEB 10, 2004			
	018554	001	FLUTAMIDE;EULEXIN	4472382	SEP 18, 2001	U-24		
				5712251	SEP 18, 2001	U-216		
>ADD>	020121	001	FLUTICASONE PROPIONATE;FLONASE				I-224	OCT 31, 2000
>ADD>	020450	001	FOSPHENYTOIN SODIUM;CEREBYX	4260769	APR 07, 1999			
	020695	001	GREPAFLOXACIN HYDROCHLORIDE;RAXAR	5563138	OCT 08, 2013			
	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
>ADD>	016295	002	HYDROXYUREA;DROXIA				ODE	FEB 25, 2005
>ADD>	016295	003	HYDROXYUREA;DROXIA				ODE	FEB 25, 2005
>ADD>	016295	004	HYDROXYUREA;DROXIA				ODE	FEB 25, 2005
	020812	001	IBUPROFEN;PEDIATRIC ADVIL				NP	JUN 16, 1998
	020393	001	IPRATROPIUM BROMIDE;ATROVENT				I-223	APR 01, 2001
	019927	001	KETOCONAZOLE;NIZORAL	4942162	FEB 11, 2003			
>ADD>	020406	001	LANSOPRAZOLE;PREVACID				I-227	MAR 12, 2001
>ADD>	020406	002	LANSOPRAZOLE;PREVACID				I-227	MAR 12, 2001
>ADD>	020807	001	LEPIRUDIN;REFLUDAN	5180668	JAN 19, 2010		ODE	MAR 06, 2005
							NCE	MAR 06, 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			
	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
>ADD>	020606	001	LOPERAMIDE HYDROCHLORIDE;IMODIUM ADVANCED	5716641	MAY 21, 2012	U-226		
>ADD>	020803	001	LOTEPREDNOL ETABONATE;ALREX	4996335	FEB 26, 2008		NCE	MAR 09, 2003
>ADD>				5540930	OCT 25, 2013			
>ADD>	020583	001	LOTEPREDNOL ETABONATE;LOTEMAX	4996335	FEB 26, 2008		NCE	MAR 09, 2003
>ADD>				5540930	OCT 25, 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
>ADD>	020841	001	LOTEPREDNOL ETABONATE;LOTEMAX	4996335	FEB 26, 2008		NCE	MAR 09, 2003
>ADD>				5540930	OCT 25, 2013			
>ADD>	019618	001	MESALAMINE;ROWASA	4657900	APR 14, 2004			
>ADD>				RE33239	MAY 12, 2004			
>ADD>	020208	001	METRONIDAZOLE;METROGEL-VAGINAL				D-40	MAY 16, 2000
	020827	001	MICONAZOLE NITRATE;MONISTAT 3				NP	MAR 30, 2001
	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
>ADD>	020536	001	NICOTINE;NICOTROL	4915950	FEB 12, 2008			
	020555	001	NIZATIDINE;AXID AR				I-220	APR 01, 2001
							D-39	APR 01, 2001
	020799	001	OFLOXACIN;FLOXIN				NDF	DEC 16, 2000
>ADD>	020262	001	PACLITAXEL;TAXOL				I-226	APR 09, 2001
	020237	001	PILOCARPINE HYDROCHLORIDE;SALAGEN				ODE	FEB 11, 2005
							I-212	FEB 11, 2001
>ADD>	019898	002	PRAVASTATIN SODIUM;PRAVACHOL				I-225	MAR 27, 2001
>ADD>	019898	003	PRAVASTATIN SODIUM;PRAVACHOL				I-225	MAR 27, 2001
>ADD>	019898	004	PRAVASTATIN SODIUM;PRAVACHOL				I-225	MAR 27, 2001
>ADD>	019781	001	PROGESTERONE;PROMETRIUM				NP	MAY 14, 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		
>ADD>	020835	001	RISEDRONATE SODIUM;ACTONEL	5583122	DEC 10, 2013	U-222	NCE	MAR 27, 2003
	020272	005	RISPERIDONE;RISPERDAL	5158952	OCT 27, 2009		D-37	OCT 17, 2000
	020236	001	SALMETEROL XINAFOATE;SEREVENT				I-216	FEB 05, 2001
>ADD>	020895	001	SILDENAFIL CITRATE;VIAGRA	5250534	JUN 18, 2011		NCE	MAR 27, 2003
>ADD>	020895	002	SILDENAFIL CITRATE;VIAGRA	5250534	JUN 18, 2011		NCE	MAR 27, 2003
>ADD>	020895	003	SILDENAFIL CITRATE;VIAGRA	5250534	JUN 18, 2011		NCE	MAR 27, 2003
	019676	001	SOMATROPIN, BIOSYNTHETIC;NUTROPIN				ODE	OCT 29, 2004
	019676	002	SOMATROPIN, BIOSYNTHETIC;NUTROPIN				ODE	OCT 29, 2004
	020181	001	SOYBEAN OIL;LIPOSYN III 30%				NP	JAN 13, 2001
>ADD>	020772	001	SUCRASE;SUCRAID				ODE	APR 09, 2005
>ADD>							NCE	APR 09, 2003
	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		
>ADD>	020771	001	TOLTERODINE TARTRATE;DETROL	5382600	JAN 17, 2012		NCE	MAR 25, 2003
>ADD>	020771	002	TOLTERODINE TARTRATE;DETROL	5382600	JAN 17, 2012		NCE	MAR 25, 2003
	020137	002	TORSEMIDE;DEMADEX				D-38	FEB 13, 2001

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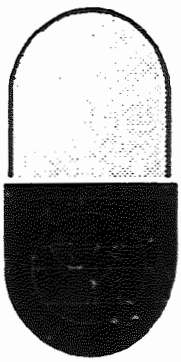

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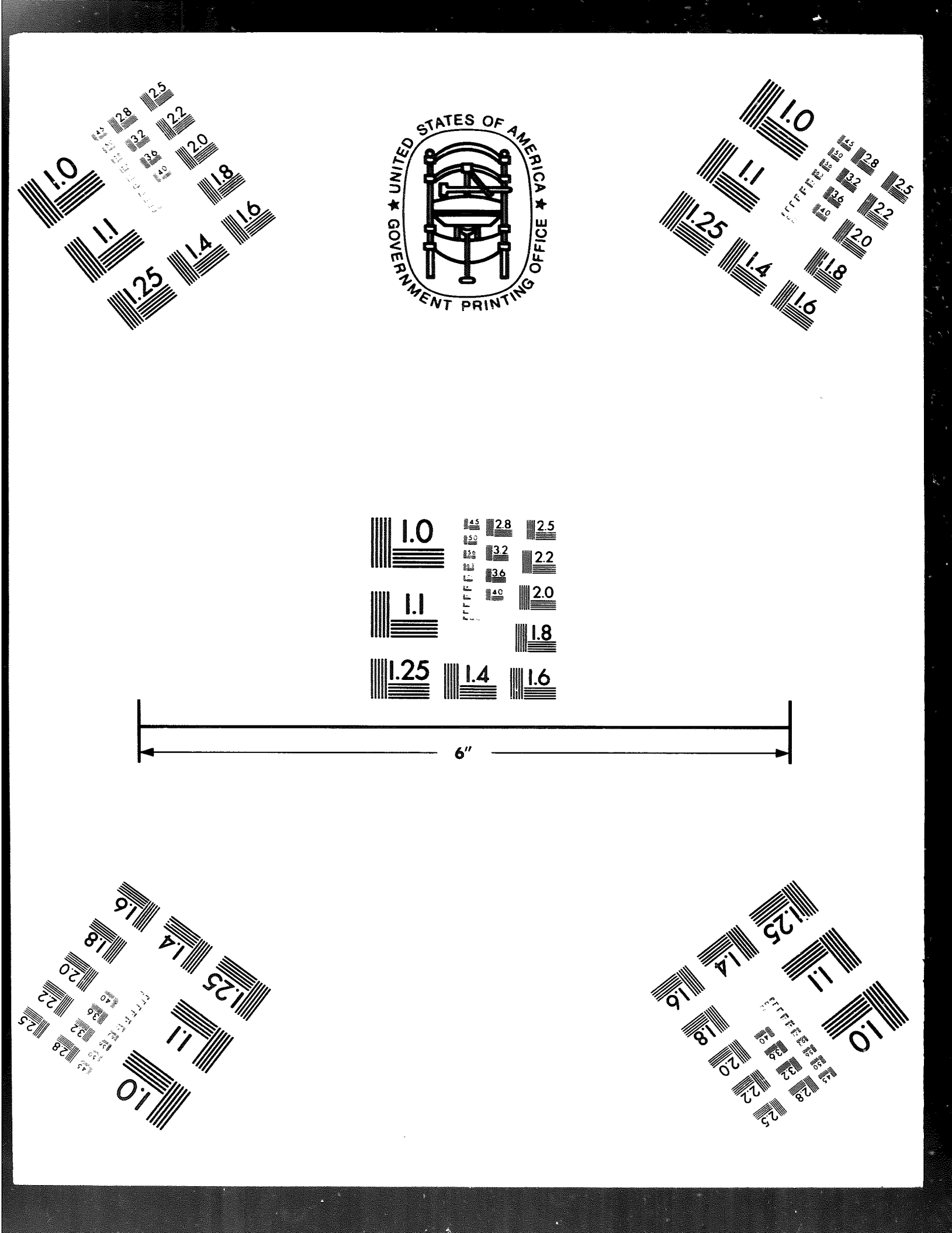
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