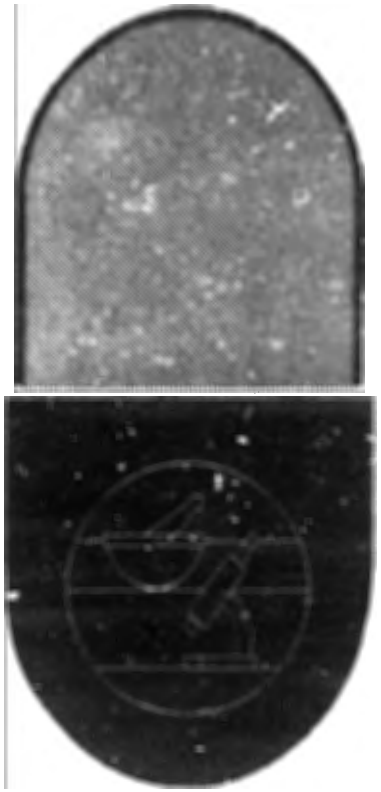
CUMULATIVE SUPPLEMENT 2
JAN'98-FEB'98



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

18TH 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

1998

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Cumulative Supplement 2

FEBRUARY 1998

CONTENTS

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CUMULATIVE SUPPLEMENT 2
FEBRUARY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 - FEBRUARY 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

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

		● BAYER	25MG	N20482 004
				MAY 29, 1997
			25MG	N20482 004
				MAY 29, 1997

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE

> DLT >	AA	ROYCE LABS	300MG;15MG	N89997 001
> DLT >				DEC 28, 1994
> DLT >	AA		300MG;30MG	N89998 001
> DLT >				DEC 28, 1994
> DLT >	AA		300MG;60MG	N89999 001
> DLT >				DEC 28, 1994
> ADD >	AA	WATSON LABS	300MG;15MG	N89997 001
> ADD >				DEC 28, 1994
> ADD >	AA		300MG;30MG	N89998 001
> ADD >				DEC 28, 1994
> ADD >	AA		300MG;60MG	N89999 001
> ADD >				DEC 28, 1994

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

> ADD >	AA	MALLINCKRODT	500MG;7.5MG	N40201 001
> ADD >				FEB 27, 1998
> ADD >	AA		500MG;10MG	N40201 002
> ADD >				FEB 27, 1998
> DLT >	AA	ROYCE LABS	500MG;7.5MG	N40121 003
> DLT >				MAR 04, 1996
> DLT >	AA		500MG;5MG	N40122 001
> DLT >				MAR 04, 1996
> DLT >	AA		500MG;7.5MG	N40123 004
> DLT >				MAR 04, 1996
> DLT >	AA		650MG;7.5MG	N40123 001
> DLT >				MAR 04, 1996
> DLT >	AA		650MG;10MG	N40123 002
> DLT >				MAR 04, 1996
> DLT >	AA		750MG;7.5MG	N40122 002
> DLT >				MAR 04, 1996

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

> ADD >	AA	WATSON LABS	500MG;2.5MG	N40123 003
> ADD >				MAR 04, 1996
> ADD >	AA		500MG;5MG	N40122 001
> ADD >				MAR 04, 1996
> ADD >	AA		500MG;7.5MG	N40123 004
> ADD >				MAR 04, 1996
> ADD >	AA		650MG;7.5MG	N40123 001
> ADD >				MAR 04, 1996
> ADD >	AA		650MG;10MG	N40123 002
> ADD >				MAR 04, 1996
> ADD >	AA		750MG;7.5MG	N40122 002
> ADD >				MAR 04, 1996

ACETAMINOPHEN; OXYCODONE

CAPSULE; ORAL
OXYCODONE AND ACETAMINOPHEN

	AA	HALSEY	500MG;5MG	N40219 001
				JAN 22, 1998

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL
OXYCODONE AND ACETAMINOPHEN

> DLT >	AA	ROYCE LABS	500MG;5MG	N40234 001
> DLT >				OCT 30, 1997
> ADD >	AA	WATSON LABS	500MG;5MG	N40234 001
> ADD >				OCT 30, 1997

TABLET; ORAL
OXYCODONE AND ACETAMINOPHEN

> DLT >	AA	ROYCE LABS	325MG;5MG	N40171 001
> DLT >				OCT 30, 1997
> ADD >	AA	WATSON LABS	325MG;5MG	N40171 001
> ADD >				OCT 30, 1997

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL
PROPOXYPHENE HCL AND ACETAMINOPHEN

> DLT >	AA	ROYCE LABS	650MG;65MG	N40139 001
> DLT >				DEC 16, 1996

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL
PROPOXYPHENE HCL AND ACETAMINOPHEN

>ADD > >ADD	AA	WATSON LABS	650MG;65MG	N40139 001 DEC 16, 1996	

ACYCLOVIR

TABLET; ORAL
ACYCLOVIR

	*	NOVOPHARM	200MG	N74556 001 APR 22, 1997	
	@		200MG	N74556 001 APR 22, 1997	

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
ACYCLOVIR SODIUM

>ADD > >ADD >	AP	APOTHECON	EQ 500MG BASE/VIAL	N74897 001 FEB 27, 1998	
>ADD > >ADD >	AP		EQ 1GM BASE/VIAL	N74897 002 FEB 27, 1998	

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

	AN	HI TECH PHARMA	EQ 0.5% BASE	N74543 001 JAN 15, 1998	

SYRUP; ORAL
ALBUTEROL SULFATE

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

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM

>DLT > >DLT >	AB	ROYCE LABS	0.25MG	N74479 001 JAN 21, 1997	
>DLT > >DLT >	AB		0.5MG	N74479 002 JAN 21, 1997	
>DLT > >DLT >	AB		1MG	N74479 003 JAN 21, 1997	
>ADD > >ADD >	AB	WATSON LABS	0.25MG	N74479 001 JAN 21, 1997	
>ADD > >ADD >	AB		0.5MG	N74479 002 JAN 21, 1997	
>ADD > >ADD >	AB		1MG	N74479 003 JAN 21, 1997	

ALPROSTADIL

INJECTABLE; INJECTION
ALPROSTADIL

	AP	BEDFORD	0.5MG/ML	N74815 001 JAN 20, 1998	

PROSTIN VR PEDIATRIC

	AP	+ PHARMACIA AND UPJOHN	0.5MG/ML	N18484 001	
		*	0.5MG/ML	N18484 001	

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

>DLT > >DLT >	AB	ROYCE LABS	EQ 5MG ANHYDROUS;50MG	N73334 001 JUL 19, 1991	
>ADD > >ADD >	AB	WATSON LABS	EQ 5MG ANHYDROUS;50MG	N73334 001 JUL 19, 1991	

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

>DLT > >DLT >	AB	ROYCE LABS	10MG;2MG	N73007 001 OCT 17, 1991	
>DLT > >DLT >	AB		10MG;4MG	N73009 001 OCT 17, 1991	
>DLT > >DLT >	AB		25MG;2MG	N73008 001 OCT 17, 1991	
>DLT > >DLT >	AB		25MG;4MG	N73010 001 OCT 17, 1991	
>ADD > >ADD >	AB	WATSON LABS	10MG;2MG	N73007 001 OCT 17, 1991	

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

> ADD >	AB	WATSON LABS	10MG;4MG	N73009 001	
> ADD				OCT 17, 1991	
> ADD >	AB		25MG;2MG	N73008 001	
> ADD >				OCT 17, 1991	
> ADD >	AB		25MG;4MG	N73010 001	
> ADD >				OCT 17, 1991	

AMRINONE LACTATE

INJECTABLE; INJECTION
INOCOR

SANOFI	EQ 5MG BASE/ML	N18700 001	
		JUL 31, 1984	
+	EQ 5MG BASE/ML	N18700 001	
		JUL 31, 1984	

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL
OXYCODONE AND ASPIRIN

> ADD >	AA	WATSON LABS	325MG;4.5MG;0.38MG	N40255 001	
> ADD >				FEB 27, 1998	

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
BACITRACIN ZINC AND POLYMYXIN B SULFATE

AT	ADV REMEDIES	500 UNITS/GM; 10,000 UNITS/GM	N64028 001	
			JAN 30, 1995	
AT	AKORN	500 UNITS/GM; 10,000 UNITS/GM	N64028 001	
			JAN 30, 1995	

BACLOFEN

TABLET; ORAL
BACLOFEN

> DLT >	AB	ROYCE LABS	10MG	N73091 001	
> DLT >				JAN 28, 1994	

BACLOFEN

TABLET; ORAL
BACLOFEN

> DLT >	AB	ROYCE LABS	20MG	N73093 001	
> DLT				JAN 28, 1994	
> ADD >	AB	WATSON LABS	10MG	N73092 001	
> ADD >				JAN 28, 1994	
> ADD >	AB		20MG	N73093 001	
> ADD >				JAN 28, 1994	

BROMOCRIPTINE MESYLATE

TABLET; ORAL
BROMOCRIPTINE MESYLATE

AB	LEK PHARM	EQ 2.5MG BASE	N74631 001	
			JAN 13, 1998	

PARLODEL

AB	+ NOVARTIS	EQ 2.5MG BASE	N17962 001	

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

> DLT >	AB	ROYCE LABS	12.5MG	N74451 001	
> DLT >				FEB 13, 1996	
> DLT >	AB		25MG	N74451 002	
> DLT >				FEB 13, 1996	
> DLT >	AB		50MG	N74451 003	
> DLT >				FEB 13, 1996	
> DLT >	AB		100MG	N74451 004	
> DLT >				FEB 13, 1996	
> ADD >	AB	WATSON LABS	12.5MG	N74451 001	
> ADD >				FEB 13, 1996	
> ADD >	AB		25MG	N74451 002	
> ADD >				FEB 13, 1996	
> ADD >	AB		50MG	N74451 003	
> ADD >				FEB 13, 1996	
> ADD >	AB		100MG	N74451 004	
> ADD >				FEB 13, 1996	

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE; ORAL
CARBATROL

+ ATHENA	200MG	N20713 001		
		SEP 30, 1997		

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE; ORAL
CARBATROL

*	ATHENA	300MG	N20712 002	SEP 30, 1997
+	SHIRE	200MG	N20712 001	SEP 30, 1997
+		300MG	N20712 002	SEP 30, 1997

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

> DLT >	AA	ROYCE LABS	350MG	N40151 001	DEC 01, 1996
> DLT >					
> ADD >	AA	WATSON LABS	350MG	N40152 001	DEC 03, 1996
> ADD >					

CEFACLOR

POWDER FOR RECONSTITUTION; ORAL
CEFACLOR

> ADD >	AB	MARSAM	EQ 125MG BASE/5ML	M64204 001	FEB 18, 1998
> ADD >					
> ADD >	AB		EQ 187MG BASE/5ML	M64205 001	FEB 18, 1998
> ADD >					
> ADD >	AB		EQ 250MG BASE/5ML	M64206 001	FEB 18, 1998
> ADD >					
> ADD >	AB		EQ 375MG BASE/5ML	M64207 001	FEB 18, 1998
> ADD >					

CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION
CHLOROMYCETIN

> DLT >	AP	* PARKE DAVIS	EQ 1GM BASE/VIAL	M50155 001	
> ADD >	AP	+ PARKEDALE	EQ 1GM BASE/VIAL	M50155 001	

CHLORDIAZEPOXIDE

TABLET; ORAL
LIBRITABS

	* ICN	5MG	N85482 001	
> DLT >				
> DLT >				

CHLORDIAZEPOXIDE

TABLET; ORAL
LIBRITABS

	* ICN	10MG	N85481 001	
		25MG	N85488 001	
	* ROCHE	5MG	N85482 001	
		10MG	N85481 001	
		25MG	N85488 001	

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
LIBRIUM

AB	ICN	5MG	N85461 001	
AB		10MG	N85472 001	
AB	+	25MG	N85475 001	
AB	ROCHE	5MG	N85461 001	
AB		10MG	N85472 001	
AB	*	25MG	N85475 001	

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
PERIDEX

AT	* PROCTER AND GAMBLE	0.12%	N19028 001	AUG 13, 1986
AT	+ ZILA	0.12%	N19028 001	AUG 13, 1986

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

> DLT >	AP	MARSAM	25MG/ML	N89563 001	APR 15, 1988
> DLT >					
> ADD >		@	25MG/ML	N89563 001	APR 15, 1988
> ADD >					

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

> DLT >	AA	ROYCE LABS	500MG	N81040 001	AUG 22, 1989
> DLT >					

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

> ADD >	AA	WATSON LABS	500MG	N81040 001	
> ADD				AUG 22, 1989	

> ADD > CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE

> ADD > SUSPENSION/DROPS; OTIC
> ADD > CIPRO HC

> ADD >	+	BAYER	EQ 0.2% BASE;1%	N20805 001
> ADD >				FEB 10, 1998

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

> DLT >	AP	MARSAM	EQ 150MG BASE/ML	N62913 001
> DLT >				OCT 20, 1988
> ADD >		@	EQ 150MG BASE/ML	N62913 001
> ADD >				OCT 20, 1988

SOLUTION; TOPICAL
CLEOCIN T

> DLT >	AP	PHARMACIA AND UPJOHN	EQ 1% BASE	N62363 001
> DLT >				FEB 08, 1982
> ADD >		@	EQ 1% BASE	N62363 001
> ADD >				FEB 08, 1982

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
CROLOM

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

OPTICROM

	AT	+ ALLERGAN	4%	N18155 001
				OCT 03, 1984
		@ RHONE POULENC RORER	4%	N18155 001
				OCT 03, 1984

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL

> DLT >	AB	ROXANE LABS	10MG	N74434 001
> DLT >				NOV 30, 1994
> ADD >	AB	WATSON LABS	10MG	N74436 001
> ADD >				NOV 30, 1994

DACTINOMYCIN

INJECTABLE; INJECTION
COSMEGEN

> ADD >	+	MERCK	0.5MG/VIAL	N50682 001
> DLT >	+	MERCK SHARP DOHME	0.5MG/VIAL	N50682 001

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

AEROSOL, METERED; INHALATION
DECADRON

	+	MEDEVA	EQ 0.1MG PHOSPHATE/INH	N13413 001
	@		EQ 0.1MG PHOSPHATE/INH	N13413 001

> DLT > DISC; NASAL
> DLT > DECADRON

> DLT >	+	MEDEVA	EQ 0.1MG PHOSPHATE/INH	N14242 001
> ADD >	@		EQ 0.1MG PHOSPHATE/INH	N14242 001

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM

>DLT>	AP	MARSAM	5MG/ML	N72371 001 JAN 29, 1993	
>DLT>					
>ADD>		@	5MG/ML	N72371 001 JAN 29, 1993	
>ADD>					

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
TIAZAC

>DLT>		+ BIOVAIL	360MG	N20401 005 SEP 11, 1995	
>DLT>					
>ADD>			360MG	N20401 005 SEP 11, 1995	
>ADD>					

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL
DIPHENHYDRAMINE HCL

>DLT>	AA	PUREPAC PHARM	12.5MG/5ML	N83237 001 JAN 25, 1982	
>DLT>					
>ADD>		@	12.5MG/5ML	N83237 001 JAN 25, 1982	
>ADD>					

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTAMINE HCL

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

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL

>DLT>	AB	ROYCE LABS	EQ 10MG BASE	N72985 001 MAR 29, 1991	
>DLT>					
>DLT>	AB		EQ 25MG BASE	N72986 001 MAR 29, 1991	
>DLT>					
>DLT>	AB		EQ 50MG BASE	N72987 001 MAR 29, 1991	
>DLT>					

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL

>ADD>	AB	WATSON LABS	EQ 10MG BASE		N72985 001 MAR 29, 1991
>ADD>					
>ADD>	AB		EQ 25MG BASE		N72986 001 MAR 29, 1991
>ADD>					
>ADD>	AB		EQ 50MG BASE		N72987 001 MAR 29, 1991
>ADD>					

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
EDROPHONIUM CHLORIDE

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

ENOXAPARIN SODIUM

INJECTABLE; INJECTION
LOVENOX

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

ERYTHROMYCIN

OINTMENT; OPHTHALMIC
ERYTHROMYCIN

	AE	AEV REMEDIES	0.5%		M64039 001 JUL 18, 1996
	AT	AKORN	0.5%		M64030 001 JUL 18, 1996

OINTMENT; TOPICAL
AKNE-MYCIN

		+ CTX LABS	2%		N50584 001 JAN 10, 1985
		+ HEALTHPOINT	2%		N50584 001 JAN 10, 1985

TABLET, DELAYED RELEASE; ORAL
E-MYCIN

>DLT>	AB	+ KNOLL PHARM	333MG		N60272 002
>ADD>	AB		333MG		N60272 002

ERY-TAB

>DLT>	AB	ABBOTT	333MG		N62298 001

ERYTHROMYCIN

TABLET, DELAYED RELEASE; ORAL
ERY-TAB

> ADD >	AB	+	ABBOTT	250MG	N62298 001
> DLT >	AB			333MG	N62298 003
					MAR 29, 1982
> DLT >					
> ADD >	AB	+		333MG	N62298 003
					MAR 29, 1982
> ADD >					
> DLT >	AB			500MG	N62298 002
> ADD >	AB	+		500MG	N62298 002

ESTAZOLAM

TABLET; ORAL
ESTAZOLAM

> DLT >	AB		ROYCE LABS	1MG	N74818 001
					AUG 19, 1997
> DLT >					
> DLT >	AB			2MG	N74818 002
					AUG 19, 1997
> DLT >					
> ADD >	AB		WATSON LABS	1MG	N74818 001
					AUG 19, 1997
> ADD >					
> ADD >	AB			2MG	N74818 002
					AUG 19, 1997
> ADD >					

ESTRADIOL

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
THEELIN

> DLT >	@		PARKE DAVIS	1MG/ML	N03977 001
> DLT >	@			2MG/ML	N03977 002
> DLT >	@			5MG/ML	N03977 003
> ADD >	@		PARKEDALE	1MG/ML	N03977 001
> ADD >	@			2MG/ML	N03977 002
> ADD >	@			5MG/ML	N03977 003

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21
LEVORA 0.15/30-21

AB		SEARLE	0.03MG;0.15MG	N73592 001
				DEC 13, 1993
AB		WATSON LABS	0.03MG;0.15MG	N73592 001
				DEC 13, 1993

TABLET; ORAL-28
LEVORA 0.15/30-28

AB		SEARLE	0.03MG;0.15MG	N73594 001
				DEC 13, 1993
AB		WATSON LABS	0.03MG;0.15MG	N73594 001
				DEC 13, 1993

ETODOLAC

CAPSULE; ORAL
ETODOLAC

AB		AESGEN	300MG	N74929 001
				JAN 30, 1998

TABLET; ORAL
ETODOLAC

> ADD >	AB		MYLAN	400MG	N75104 001
					FEB 06, 1998
> ADD >					
> DLT >	AB		ROYCE LABS	400MG	N74892 001
					APR 16, 1997
> DLT >					
> ADD >	AB		WATSON LABS	400MG	N74892 001
					APR 16, 1997
> ADD >					

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

DLT		ETOPOPHOS			
DLT	+	BRISTOL MYERS SQUIBB	EQ 100MG BASE/VIAL	N20457 001	MAY 17, 1996
DLT					
ADD		ETOPOPHOS PRESERVATIVE FREE			
ADD	+	BRISTOL MYERS SQUIBB	EQ 100MG BASE/VIAL	N20457 001	MAY 17, 1996
ADD					
ADD	+		EQ 500MG BASE/VIAL	N20906 001	FEB 27, 1998
ADD					

FENFLURAMINE HYDROCHLORIDE

TABLET; ORAL

	PONDIMIN			
	+ ROBINS AH	20MG	N16618 001	
	@	20MG	N16618 001	

FENOFIBRATE

CAPSULE; ORAL

	LIPIDIL			
ADD	@ ABBOTT	100MG	N19304 001	DEC 31, 1993
ADD				
DLT	@ LABS FOURNIER	100MG	N19304 001	DEC 31, 1993
DLT				
ADD	TRICOR (MICRONIZED)			
ADD	+ ABBOTT	67MG	N19304 002	FEB 09, 1998
ADD				

FENTANYL CITRATE

INJECTABLE; INJECTION

DLT		FENTANYL CITRATE			
DLT	AP	ABBOTT	EQ 0.05MG BASE/ML	N72786 001	SEP 24, 1991
DLT					
DLT	AP +	ELKINS SINN	EQ 0.05MG BASE/ML	N19101 001	JUL 11, 1984
DLT					
ADD		FENTANYL CITRATE PRESERVATIVE FREE			
ADD	AP	ABBOTT	EQ 0.05MG BASE/ML	N72786 001	SEP 24, 1991
ADD					
ADD	AP +	ELKINS SINN	EQ 0.05MG BASE/ML	N19101 001	JUL 11, 1984
ADD					
ADD	AP	MARSAM	EQ 0.05MG BASE/ML	N74917 001	FEB 03, 1998
ADD					

FENTANYL CITRATE

INJECTABLE; INJECTION

DLT		SUBLIMAZE			
DLT	AP +	JANSSEN	EQ 0.05MG BASE/ML	N16619 001	
ADD		SUBLIMAZE PRESERVATIVE FREE			
ADD	AP +	JANSSEN	EQ 0.05MG BASE/ML	N16619 001	

FLUVOXAMINE MALEATE

TABLET; ORAL

	LUVOX			
DLT	@ SOLVAY	25MG	N20243 001	DEC 05, 1994
DLT				
ADD		25MG	N20243 001	DEC 05, 1994
ADD				

GEMFIBROZIL

TABLET; ORAL

	LOPID				
DLT	AB +	PARKE DAVIS	600MG	N18422 001	NOV 20, 1986
DLT					
ADD	AB +	PARKE DAVIS PHARMS	600MG	N18422 003	NOV 20, 1986
ADD					

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

	GUANFACINE HCL				
DLT	AB	ROYCE LABS	EQ 1MG BASE	N74762 001	JUN 25, 1997
DLT					
DLT	AB		EQ 2MG BASE	N74762 002	JUN 25, 1997
DLT					
ADD	AB	WATSON LABS	EQ 1MG BASE	N74762 001	JUN 25, 1997
ADD					
ADD	AB		EQ 2MG BASE	N74762 002	JUN 25, 1997
ADD					

HALOPERIDOL

TABLET; ORAL

	HALOPERIDOL				
DLT	AB	PUREPAC PHARM	0.5MG	N71071 001	NOV 03, 1988
DLT					

HALOPERIDOL

TABLET; ORAL
HALOPERIDOL

> DLT >	AB	PUREPAC PHARM	1MG	N71072 001	
> DLT				NOV 03, 1986	> ADD >
> DLT >	AB		2MG	N71073 001	> ADD >
> DLT				NOV 03, 1986	> ADD >
> DLT >	AB		5MG	N71074 001	> ADD >
> DLT				NOV 03, 1986	> DLT >
> DLT >	AB		10MG	N71075 001	> DLT >
> DLT				AUG 04, 1987	> DLT >
> DLT >	AB		20MG	N71076 001	> DLT >
> DLT				AUG 04, 1987	
> ADD >		@	0.5MG	N71071 001	
> ADD				NOV 03, 1986	> ADD >
> ADD >		@	1MG	N71072 001	> ADD >
> ADD				NOV 03, 1986	> DLT >
> ADD >		@	2MG	N71073 001	> DLT >
> ADD				NOV 03, 1986	
> ADD >		@	5MG	N71074 001	
> ADD				NOV 03, 1986	> ADD >
> ADD >		@	10MG	N71075 001	> ADD >
> ADD				AUG 04, 1987	> DLT >
> ADD >		@	20MG	N71076 001	> DLT >
> ADD >				AUG 04, 1987	

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE

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

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL

> DLT >	AP	MARSAM	EQ 5MG BASE/ML	N72516 001	
> DLT				FEB 25, 1993	> ADD >
> DLT >	AP		EQ 5MG BASE/ML	N72517 001	> ADD >
> DLT				FEB 25, 1993	> DLT >
> ADD >		@	EQ 5MG BASE/ML	N72516 001	> DLT >
> ADD				FEB 25, 1993	
> ADD >		@	EQ 5MG BASE/ML	N72517 001	
> ADD				FEB 25, 1993	> ADD >
					> ADD >

HEPARIN SODIUM

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

> ADD >	AP	B BRAUN	200 UNITS/100ML	N19953 001
> ADD >				JUL 20, 1992
> ADD >		@	200 UNITS/100ML	N19042 001
> ADD >				MAR 29, 1985
> DLT >	AP	MCGAW	200 UNITS/100ML	N19953 001
> DLT >				JUL 20, 1992
> DLT >		@	200 UNITS/100ML	N19042 001
> DLT >				MAR 29, 1985

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

> ADD >		@ B BRAUN	5,000 UNITS/100ML	N19802 001
> ADD >				JUL 20, 1992
> DLT >		@ MCGAW	5,000 UNITS/100ML	N19802 001
> DLT >				JUL 20, 1992

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

> ADD >		@ B BRAUN	200 UNITS/100ML	N19042 002
> ADD >				MAR 29, 1985
> DLT >		@ MCGAW	200 UNITS/100ML	N19042 002
> DLT >				MAR 29, 1985

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

> ADD >	AP	B BRAUN	4,000 UNITS/100ML	N19952 001
> ADD >				JUL 20, 1992
> DLT >	AP	MCGAW	4,000 UNITS/100ML	N19952 001
> DLT >				JUL 20, 1992

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

> ADD >	AP	B BRAUN	5,000 UNITS/100ML	N19952 004
> ADD >				JUL 20, 1992
> ADD >	AP		10,000 UNITS/100ML	N19952 005
> ADD >				JUL 20, 1992
> ADD >		@	5,000 UNITS/100ML	N19134 001
> ADD >				MAR 29, 1985
> DLT >	AP	MCGAW	5,000 UNITS/100ML	N19952 004
> DLT >				JUL 20, 1992
> DLT >	AP		10,000 UNITS/100ML	N19952 005
> DLT >				JUL 20, 1992
> DLT >		@	5,000 UNITS/100ML	N19134 001
> DLT >				MAR 29, 1985

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

> ADD >		@ B BRAUN	5,000 UNITS/100ML	N19802 005
> ADD >				JUL 20, 1992

HEPARIN SODIUM

INJECTABLE; INJECTION

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

> ADD >	@ B BRAUN	10,000 UNITS/100ML	N19802 002	JUL 20, 1992
> ADD >				
> DLT >	@ MCGAW	5,000 UNITS/100ML	N19802 005	JUL 20, 1992
> DLT >				
> DLT >	@	10,000 UNITS/100ML	N19802 002	JUL 20, 1992
> DLT >				

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

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

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

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

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

> ADD >	AVAPRO HCT			
> ADD >	@ SANOFI	12.5MG;75MG	N20758 001	SEP 30, 1997
> ADD >				
> ADD >	+	12.5MG;150MG	N20758 002	SEP 30, 1997
> ADD >				
> DLT >	IRBESARTAN-HYDROCHLOROTHIAZIDE			
> DLT >	@ SANOFI	12.5MG;75MG	N20758 001	SEP 30, 1997
> DLT >				
> DLT >	+	12.5MG;150MG	N20758 002	SEP 30, 1997
> DLT >				

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

> DLT >	AB	INVAMED	15MG;250MG	N70829 001 MAR 09, 1987
> DLT >				

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

> DLT >	AB	INVAMED	25MG;250MG	N70830 001 MAR 09, 1987
> DLT >				
> ADD >	@		15MG;250MG	N70829 001 MAR 09, 1987
> ADD >				
> ADD >	@		25MG;250MG	N70830 001 MAR 09, 1987
> ADD >				

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

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

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATE

> DLT >	AB	ROYCE LABS	200MG	N40133 001 NOV 10, 1995
> DLT >				
> ADD >	AB	WATSON LABS	200MG	N40133 001 NOV 30, 1995
> ADD >				

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HCL

> DLT >	AB	ROYCE LABS	10MG	N81149 001 MAR 18, 1994
> DLT >				
> DLT >	AB		25MG	N81150 001 MAR 18, 1994
> DLT >				
> DLT >	AB		50MG	N81151 001 MAR 18, 1994
> DLT >				
> ADD >	AB	WATSON LABS	10MG	N81149 001 MAR 18, 1994
> ADD >				
> ADD >	AB		25MG	N81150 001 MAR 18, 1994
> ADD >				
> ADD >	AB		50MG	N81151 001 MAR 18, 1994
> ADD >				

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S ADVIL

	BX	AM HOME PRODS	100MG/5ML	N19833 002 SEP 19, 1989	> DLT > > DLT >
	BX	WHITEHALL ROBINS	100MG/5ML	N19833 002 SEP 19, 1989	> ADD > > ADD >

TABLET; ORAL
IBUPROFEN

> DLT > > DLT >	AB	INVAMED	400MG	N72064 001 JAN 14, 1988	> DLT > > DLT >
> DLT > > DLT >	AB		600MG	N72065 001 JAN 14, 1988	> ADD > > ADD >
> DLT > > DLT >	AB		800MG	N71938 001 JAN 14, 1988	
> ADD > > ADD >		@	400MG	N72064 001 JAN 14, 1988	
> ADD > > ADD >		@	600MG	N72065 001 JAN 14, 1988	
> ADD > > ADD >		@	800MG	N71938 001 JAN 14, 1988	

INDAPAMIDE

TABLET; ORAL
INDAPAMIDE

> ADD > > ADD >	AB	TEVA	1.25MG	N74498 002 FEB 12, 1998

IOPAMIDOL

INJECTABLE; INJECTION
IOPAMIDOL-250

> ADD > > ADD >	AP	ABBOTT	51%	N75005 001 FEB 24, 1998

IOPAMIDOL-300

> ADD > > ADD >	AP	ABBOTT	61%	N75005 002 FEB 24, 1998

IOPAMIDOL-370

> ADD > > ADD >	AP	ABBOTT	76%	N75005 003 FEB 24, 1998

IOTROLAN

INJECTABLE; INTRATHECAL
OSMOVIST 190

	BERLEX	40.6%	N19580 001 DEC 07, 1989
	BERLEX LABS	40.6%	N19580 001 DEC 07, 1989

OSMOVIST 240

	BERLEX	51.3%	N19580 002 DEC 07, 1989
	BERLEX LABS	51.3%	N19580 002 DEC 07, 1989

IPRATROPIUM BROMIDE

AEROSOL, METERED; INHALATION
ATROVENT

	BOEHRINGER INGELHEIM	0.018MG/INH	N19085 001 DEC 29, 1986
+		0.018MG/INH	N19085 001 DEC 29, 1986

ISOSULFAN BLUE

INJECTABLE; INJECTION
LYMPHAZURIN

#	HIKMA IMDS	1%	N18310 001
+	US SURGCL	1%	N18310 001

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL
ORUVAIL

#	WYETH AYERST	100MG	N19816 003 FEB 08, 1995
#		150MG	N19816 002 FEB 08, 1995
		100MG	N19816 003 FEB 08, 1995
		150MG	N19816 002 FEB 08, 1995

LIDOCAINE; PRILOCAINE

DISC; TOPICAL
EMLA

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

LORAZEPAM

TABLET; ORAL
LORAZEPAM

> DLT >	AB	ROXCE LABS	0.5MG	N72926 001 OCT 31, 1991	
> DLT >					
> DLT >	AB		1MG	N72927 001 OCT 31, 1991	
> DLT >					
> DLT >	AB		2MG	N72928 001 OCT 31, 1991	
> DLT >					
> ADD >	AB	WATSON LABS	0.5MG	N72926 001 OCT 31, 1991	
> ADD >					
> ADD >	AB		1MG	N72927 001 OCT 31, 1991	
> ADD >					
> ADD >	AB		2MG	N72928 001 OCT 31, 1991	
> ADD >					

MALATHION

LOTION; TOPICAL
OVIDE

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

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE

> ADD >	AB	PHARMACHEMIE	40MG	N74745 001 FEB 27, 1998	
> ADD >					

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL

> DLT >	AA	ROXCE LABS	50MG	[redacted] JUN 30, 1997	
> DLT >					

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL

> ADD >	AA	WATSON LABS	50MG	N40186 001 JUN 30, 1997	
> ADD >					

METHOCARBAMOL

INJECTABLE; INJECTION
METHOCARBAMOL

> DLT >	AP	NORGAN	[redacted]	[redacted] DEC 27, 1991	
> DLT >					
> ADD >		@	100MG/ML	N89849 001 DEC 27, 1991	
> ADD >					

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

> DLT >	AB	[redacted]	[redacted]	[redacted] JUN 22, 1989	
> DLT >					
> DLT >	AB		[redacted]	[redacted] FEB 03, 1987	
> DLT >					
> ADD >		@	EQ 5MG BASE	N72436 001 JUN 22, 1989	
> ADD >					
> ADD >		@	EQ 10MG BASE	N70850 001 FEB 03, 1987	
> ADD >					

MONTELUKAST SODIUM

TABLET; ORAL
SINGULAR

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

TABLET, CHEWABLE; ORAL
SINGULAIR

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

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES

> DLT >	AB	ROYCE LABS	EQ 0.5MG BASE;		
> DLT >			EQ 50MG BASE	N74736 001	
> DLT >				JAN 21, 1997	
> ADD >	AB	WATSON LABS	EQ 0.5MG BASE;		
> ADD >			EQ 50MG BASE	N74736 001	
> ADD >				JAN 21, 1997	

NAPROXEN

TABLET, DELAYED RELEASE; ORAL

EC-NAPROSYN

> ADD >	AB	+ SYNTEX	375MG	N20067 002	
> ADD >				OCT 14, 1994	
> ADD >	AB	+	500MG	N20067 003	
> ADD >				OCT 14, 1994	

NAPROXEN

> ADD >	AB	INVAMED	375MG	N75061 001	
> ADD >				FEB 18, 1998	
> ADD >	AB		500MG	N75061 002	
> ADD >				FEB 18, 1998	
> ADD >	AB	PUREPAC PHARM	375MG	N74936 001	
> ADD >				FEB 24, 1998	
> ADD >	AB		500MG	N74936 002	
> ADD >				FEB 24, 1998	

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

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

NARATRIPTAN HYDROCHLORIDE

TABLET; ORAL

AMERGE

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

NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION; IRRIGATION

NEOSPORIN G.U. IRRIGANT

AT	GLAXO WELLCOME	EQ 40MG BASE/ML;		
		200,000 UNITS/ML	N60707 001	
AT	MONARCH PHARMS	EQ 40MG BASE/ML;		
		200,000 UNITS/ML	N60707 001	

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

MINITRAN

> DLT >	AB	3M	0.1MG/HR	N89771 001
> DLT >				AUG 30, 1996
> ADD >	AB1		0.1MG/HR	N89771 001
> ADD >				AUG 30, 1996
> DLT >	AB		0.2MG/HR	N89772 001
> DLT >				AUG 30, 1996
> ADD >	AB1		0.2MG/HR	N89772 001
> ADD >				AUG 30, 1996
> DLT >	AB		0.4MG/HR	N89773 001
> DLT >				AUG 30, 1996
> ADD >	AB1		0.4MG/HR	N89773 001
> ADD >				AUG 30, 1996
> DLT >	AB		0.6MG/HR	N89774 001
> DLT >				AUG 30, 1996
> ADD >	AB1		0.6MG/HR	N89774 001
> ADD >				AUG 30, 1996

NITRO-DUR

> DLT >	AB	KEY PHARMS	0.1MG/HR	N20145 001
> DLT >				APR 04, 1995
> ADD >	AB1	+	0.1MG/HR	N20145 001
> ADD >				APR 04, 1995
> DLT >	AB	+	0.2MG/HR	N20145 002
> DLT >				APR 04, 1995
> ADD >	AB1	+	0.2MG/HR	N20145 002
> ADD >				APR 04, 1995
> DLT >	AB	+	0.4MG/HR	N20145 004
> DLT >				APR 04, 1995
> ADD >	AB1	+	0.4MG/HR	N20145 004
> ADD >				APR 04, 1995
> DLT >	AB	+	0.6MG/HR	N20145 005
> DLT >				APR 04, 1995
> ADD >	AB1	+	0.6MG/HR	N20145 005
> ADD >				APR 04, 1995

NITROGLYCERIN

> ADD >	AB2	MYLAN	0.1MG/HR	N75033 001
> ADD >				FEB 06, 1998

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

		NITROGLYCERIN			
> DLT >	AB	MYLAN	0.2MG/HR	N74609 001	AUG 30, 1996
> DLT >					
> ADD >	AB2		0.2MG/HR	N74609 001	AUG 30, 1996
> ADD >					
> DLT >	AB		0.4MG/HR	N74607 001	AUG 30, 1996
> DLT >					
> ADD >	AB2		0.4MG/HR	N74607 001	AUG 30, 1996
> ADD >					
> DLT >	AB		0.6MG/HR	N74559 001	AUG 30, 1996
> DLT >					
> ADD >	AB2		0.6MG/HR	N74559 001	AUG 30, 1996
> ADD >					
		TRANSDERM-NITRO			
> ADD >	AB2 +	NOVARTIS	0.1MG/HR	N20144 001	FEB 27, 1996
> ADD >					
> DLT >	AB +		0.2MG/HR	N20144 002	FEB 27, 1996
> DLT >					
> ADD >	AB2 +		0.2MG/HR	N20144 002	FEB 27, 1996
> ADD >					
> DLT >	AB +		0.4MG/HR	N20144 003	FEB 27, 1996
> DLT >					
> ADD >	AB2 +		0.4MG/HR	N20144 003	FEB 27, 1996
> ADD >					
> DLT >	AB +		0.6MG/HR	N20144 004	FEB 27, 1996
> DLT >					
> ADD >	AB2 +		0.6MG/HR	N20144 004	FEB 27, 1996
> ADD >					
> DLT >	BX +		0.1MG/HR	N20144 001	FEB 27, 1996
> DLT >					

NORETHINDRONE

TABLET; ORAL

		NOR-QD			
> DLT >	+	SEARLE	0.35MG	N17060 001	
> ADD >	+	WATSON LABS	0.35MG	N17060 001	

PERMETHRIN

CREAM; TOPICAL

		ELIMITE			
AB	+	ALLERGAN	5%	N19855 001	AUG 25, 1989

PERMETHRIN

CREAM; TOPICAL

		PERMETHRIN			
AB		ALPHARMA	5%	N74806 001	JAN 23, 1998

PINDOLOL

TABLET; ORAL

		PINDOLOL			
> DLT >	AB	PUREPAC PHARM	5MG	N74125 001	APR 28, 1993
> DLT >					
> DLT >	AB		10MG	N74125 002	APR 28, 1993
> DLT >					
> ADD >	@		5MG	N74125 001	APR 28, 1993
> ADD >					
> ADD >	@		10MG	N74125 002	APR 28, 1993
> ADD >					
> DLT >	AB	ROYCE LABS	5MG	N74437 001	FEB 27, 1995
> DLT >					
> DLT >	AB		10MG	N74437 002	FEB 27, 1995
> DLT >					
> ADD >	AB	WATSON LABS	5MG	N74437 001	FEB 27, 1995
> ADD >					
> ADD >	AB		10MG	N74437 002	FEB 27, 1995
> ADD >					

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION

		ZOSYN IN PLASTIC CONTAINER			
> ADD >	+	LEDERLE	EQ 40MG BASE/ML; EQ 5MG BASE/ML	N50750 001	FEB 24, 1998
> ADD >					
> ADD >	+		EQ 4GM BASE/100ML; EQ 500MG BASE/100ML	N50750 003	FEB 24, 1998
> ADD >					
> ADD >	+		EQ 60MG BASE/ML; EQ 7.5MG BASE/ML	N50750 002	FEB 24, 1998
> ADD >					

PIROXICAM

CAPSULE; ORAL
PIROXICAM

> DLT >	AB	ROYCE LABS	10MG	N74460 001	
> DLT >				SEP 29, 1995	
> DLT >	AB		20MG	N74460 002	
> DLT >				SEP 29, 1995	
> ADD >	AB	WATSON LABS	10MG	N74460 001	
> ADD >				SEP 29, 1995	
> ADD >	AB		20MG	N74460 002	
> ADD >				SEP 29, 1995	

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

POWDER FOR RECONSTITUTION; ORAL
PEG-LYTE

> DLT >	AA	INVAMED	236GM/BOT;2.97GM/BOT;6.74GM/BOT;		
> DLT >			5.86GM/BOT;22.74GM/BOT	N73098 001	
> DLT >				AUG 31, 1993	
> ADD >		@	236GM/BOT;2.97GM/BOT;6.74GM/BOT;		
> ADD >			5.86GM/BOT;22.74GM/BOT	N73098 001	
> ADD >				AUG 31, 1993	

POLYMYXIN B SULFATE

INJECTABLE; INJECTION
AEROSPORIN

> DLT >	AP	+ GLAXO WELLCOME	EQ 500,000 U BASE/VIAL	N62036 001	
> ADD >		@	EQ 500,000 U BASE/VIAL	N62036 001	
		POLYMYXIN B SULFATE			
> DLT >	AP	PFIZER	EQ 500,000 U BASE/VIAL	N60716 001	
> ADD >	AP	+	EQ 500,000 U BASE/VIAL	N60716 001	

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL
MIRAPEX

> ADD >		PHARMACIA AND UPJOHN	0.5MG	N20667 006
> ADD >				FEB 12, 1998

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE

> DLT >	BX		DANBURY PHARMA	5MG	N80354 001
> ADD >	BX	+		5MG	N80354 001
> DLT >	BX	+	GENEVA PHARMS	5MG	N80339 001
> ADD >		@		5MG	N80339 001

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL

> DLT >	AB	INVAMED	500MG	N89284 001	
> DLT >				JUN 23, 1986	
> ADD >		@	500MG	N89284 001	
> ADD >				JUN 23, 1986	

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE

> DLT >	AP	MARSAM	EQ 5MG BASE/ML	N89675 001	
> DLT >				DEC 05, 1988	
> ADD >		@	EQ 5MG BASE/ML	N89675 001	
> ADD >				DEC 05, 1988	

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCHLORPERAZINE MALEATE

> ADD >	AB	TRIGEN	EQ 5MG BASE	N40268 001	
> ADD >				FEB 27, 1998	
> ADD >	AB		EQ 10MG BASE	N40268 002	
> ADD >				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

> DLT >	AP	MARSAM	25MG/ML	N89463 001	
> DLT >				MAY 02, 1988	

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL

> DLT >	AP	MARSAM	50MG/ML	N89477 001	
> DLT >				MAY 02, 1988	
> ADD >		@	25MG/ML	N89463 001	
> ADD >				MAY 02, 1988	
> ADD >		@	50MG/ML	N89477 001	
> ADD >				MAY 02, 1988	

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL

> DLT >	AA	PUREPAC PHARM	65MG	N83278 001
> ADD >		@	65MG	N83278 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

> DLT >	AB	INVAMED	10MG	N71658 001
> DLT >				JUL 05, 1988
> DLT >	AB		20MG	N71687 001
> DLT >				JUL 05, 1988
> DLT >	AB		40MG	N71688 001
> DLT >				JUL 05, 1988
> DLT >	AB		60MG	N72197 001
> DLT >				JUL 05, 1988
> DLT >	AB		80MG	N71689 001
> DLT >				JUL 05, 1988
> DLT >	AB		90MG	N72198 001
> DLT >				JUL 05, 1988
> ADD >		@	10MG	N71658 001
> ADD >				JUL 05, 1988
> ADD >		@	20MG	N71687 001
> ADD >				JUL 05, 1988
> ADD >		@	40MG	N71688 001
> ADD >				JUL 05, 1988
> ADD >		@	60MG	N72197 001
> ADD >				JUL 05, 1988
> ADD >		@	80MG	N71689 001
> ADD >				JUL 05, 1988
> ADD >		@	90MG	N72198 001
> ADD >				JUL 05, 1988

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

> DLT >	AB	PUREPAC PHARM	200MG	N84003 001
> ADD >		@	200MG	N84003 001

RANITIDINE HYDROCHLORIDE

SYRUP; ORAL
ZANTAC

		GLAXO WELLCOME	EQ 15MG BASE/ML	N19675 001
				DEC 30, 1988
	+		EQ 15MG BASE/ML	N19675 001
				DEC 30, 1988

TABLET; ORAL
RANITIDINE HCL

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

SAQUINAVIR

CAPSULE; ORAL
FORTOVASE

> DLT >		ROCHE	EQ 200MG BASE	N20628 001
> DLT >				NOV 07, 1997
> ADD >	+		200MG	N20628 001
> ADD >				NOV 07, 1997

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
KAYEXALATE

> DLT >	AA	SANOFI	453.6GM/BOT	N11287 001
> ADD >	AA +		453.6GM/BOT	N11287 001
> ADD >		KIONEX		
> ADD >	AA	PADDOCK	454GM/BOT	N40029 001
> ADD >				FEB 06, 1998

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

> DLT >	AP	+	APOTHECON	20MG/ML	N08847 001
> ADD >			●	20MG/ML	N08847 001

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

> DLT >			[illegible]		
> DLT >	AB		TEVA	200MG/5ML;40MG/5ML	N18812 001 JAN 28, 1983
> DLT >					
> DLT >			[illegible]		
> DLT >	AB		TEVA	200MG/5ML;40MG/5ML	N18812 002 JUN 10, 1983
> DLT >					
> ADD >			SULFAMETHOXAZOLE AND TRIMETHOPRIM		
> ADD >	AB		TEVA	200MG/5ML;40MG/5ML	N18812 001 JAN 28, 1983
> ADD >					
> ADD >	AB			200MG/5ML;40MG/5ML	N18812 002 JUN 10, 1983
> ADD >					

TABLET; ORAL

> DLT >			[illegible]		
> DLT >	AB		TEVA	[illegible]	N18242 001
> DLT >	AB			[illegible]	N18242 002
> ADD >			SULFAMETHOXAZOLE AND TRIMETHOPRIM		
> ADD >	AB		TEVA	400MG;80MG	N18242 001
> ADD >	AB			800MG;160MG	N18242 002

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

AB			[illegible]	[illegible]	N89339 001 OCT 26, 1987

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

	@		SUPERPHARM	500MG	N89339 001 OCT 26, 1987

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

TECHNETIUM TC 99M ALBUMIN AGGREGATED KIT

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

TECHNETIUM TC-99M GLUCEPTATE KIT

INJECTABLE; INJECTION

TECHNESCAN GLUCEPTATE

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

TECHNETIUM TC-99M LIDOFENIN KIT

INJECTABLE; INJECTION

TECHNESCAN HIDA

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

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

TECHNESCAN MDP KIT

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

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
DTPA

AP	DRAXIMAGE	N/A	N18511 001 DEC 29, 1989	> ADD >	
AP	MERCK	N/A	N18511 001 DEC 29, 1989	> ADD >	

TECHNETIUM TC-99M SULFUR COLLOID KIT

SOLUTION; INJECTION, ORAL
AM-SULFUR COLLOID

AP	CIS	N/A	N17858 001		
	@	N/A	N17858 001		

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM

> DLT >	BX	+ THERATECH	2.5MG/24HR	N20489 001 SEP 29, 1995	
> DLT >				N20489 001 SEP 29, 1995	
> ADD >		+	2.5MG/24HR		
> ADD >					

THEOPHYLLINE

CAPSULE; ORAL
ELIXOPHYLLIN

> DLT >					
> DLT >	BX	FOREST LABS	100MG	N85545 001 JUL 31, 1984	> ADD >
> DLT >				N83921 001 JUL 31, 1984	> ADD >
> DLT >	BX	+	200MG		
> ADD >		@	100MG	N85545 001 JUL 31, 1984	
> ADD >				N83921 001 JUL 31, 1984	> ADD >
> ADD >		@	200MG		
> ADD >					

CAPSULE, EXTENDED RELEASE; ORAL
ELIXOPHYLLIN SR

> DLT >					
> DLT >	BC	FOREST LABS	125MG	N86826 001 JAN 29, 1985	> DLT >
> DLT >				N86826 002 JAN 29, 1985	> DLT >
> DLT >	BC		250MG		
> ADD >		@	125MG	N86826 001 JAN 29, 1985	> DLT >
> ADD >					

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
ELIXOPHYLLIN SR

> ADD >				
> ADD >	@	FOREST LABS	250MG	N86826 002 JAN 29, 1985
> ADD >				

TOLCAPONE

TABLET; ORAL
TASMAR

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

TRETINOIN

GEL; TOPICAL
AVITA

	PENEDERM	0.025%	N20400 001 JAN 29, 1998

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL
TRIHEXYPHENIDYL HCL

> ADD >				
> ADD >	AA	CIRCA	2MG	N40184 001 FEB 06, 1998
> ADD >				N40184 002 FEB 06, 1998
> ADD >	AA		5MG	

UROFOLLITROPIN

INJECTABLE; INTRAMUSCULAR
FERTINEX

> ADD >	+	SERONO	75 IU/AMP	N19415 002 SEP 18, 1986
> ADD >				N19415 003 SEP 18, 1986
> ADD >	+		150 IU/AMP	
> ADD >				
> DLT >		METRODIN		N19415 002 SEP 18, 1986
> DLT >	+	SERONO	75 IU/AMP	N19415 003 SEP 18, 1986
> DLT >				
> DLT >	+		150 IU/AMP	
> DLT >				

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

		VERAPAMIL HCL		
> DLT >	AP	MARSAM	2.5MG/ML	N72233 001
> DLT >				FEB 26, 1993
> DLT >	AP		2.5MG/ML	N73485 001
> DLT >				SEP 27, 1993
> ADD >		@	2.5MG/ML	N72233 001
> ADD >				FEB 26, 1993
> ADD >		@	2.5MG/ML	N73485 001
> ADD >				SEP 27, 1993

VIDARABINE

INJECTABLE; INJECTION

		VIRA-A		
> DLT >		@ PARKE DAVIS	EQ 187.4MG BASE/ML	N50523 001
> ADD >		@ PARKEDALE	EQ 187.4MG BASE/ML	N50523 001

ACETAMINOPHEN; ASPIRIN; CAFFEINE

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

CLOTRIMAZOLE

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

IBUPROFEN

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

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
NICOTROL
> DLT > + MCNEIL — 15MG/16HR — N20536 001 JUL 03, 1996
> DLT > + PHARMACIA AND UPJOHN — 15MG/16HR — N20536 001 JUL 03, 1996

RANITIDINE HYDROCHLORIDE

> ADD > TABLET, EFFERVESCENT; ORAL
ZANTAC 75
> ADD > + 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 2 FEBRUARY '98

NO FEBRUARY 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 February 1998

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Aldesleukin TN= Proleukin	Treatment of metastatic melanoma.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=09/10/1996 MA=01/09/1998
Bindarit TN=	Treatment of lupus nephritis.	Angelini Pharmaceuticals, Inc. 70 Grand Avenue River Edge, NJ 07661 DD=02/03/1998
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
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

Orphan Product Designations and Approvals List
January 1998 through February 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

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

NO FEBRUARY 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 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..."

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 RHINORRHE \ ASSOICATED WITH ALLERGIC AND NONALLERGIC PERENNIAL RHINITIS IN CHILDREN AGE 6-11 YEARS

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

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>	019787	001	AMLODIPINE BESYLATE;NORVASC	4572909	JUL 31, 2006			
>ADD>	019787	002	AMLODIPINE BESYLATE;NORVASC	4572909	JUL 31, 2006			
>ADD>	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				NCE	APR 01, 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		
	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 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
>ADD>	020869	001	DORZOLAMIDE HYDROCHLORIDE;COSOPT				NC	APR 07, 2001
	020164	001	ENOXAPARIN SODIUM;LOVENOX				I-217	JAN 30, 2001
>ADD>							I-222	MAR 27, 2001
>ADD>	020164	002	ENOXAPARIN SODIUM;LOVENOX				I-222	MAR 27, 2001
	020738	004	EPROSARTAN MESYLATE;TEVETEN	5185351	FEB 09, 2010	U-3		
	020738	005	EPROSARTAN MESYLATE;TEVETEN	5185351	FEB 09, 2010	U-3		
	083209	001	ESTROGENS, ESTERIFIED;ESTRATAB				I-214	MAR 10, 2001
	086715	001	ESTROGENS, ESTERIFIED;ESTRATAB				I-214	MAR 10, 2001
	020363	001	FAMCICLOVIR;FAMVIR				NCE	JUN 29, 1999
	020786	001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	4254129	APR 10, 1999			
				5375693	AUG 03, 2012			
				5578610	NOV 26, 2013			
>ADD>	020180	001	FINASTERIDE;PROSCAR				I-221	MAR 20, 2001
	018554	001	FLUTAMIDE;EULEXIN	4472382	SEP 18, 2001	U-24		
				5712251	SEP 18, 2001	U-216		
>ADD>	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
	016295	001	HYDROXYUREA;HYDREA				ODE	FEB 25, 2005
	020812	001	IBUPROFEN;PEDIATRIC ADVIL				NP	JUN 16, 1998

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>	020393	001	IPRATROPIUM BROMIDE;ATROVENT				I-223	APR 01, 2001
	019927	001	KETOCONAZOLE;NIZORAL	4942162	FEB 11, 2003			
>ADD>	020807	001	LEPIRUDIN;REFLUDAN				ODE	MAR 06, 2005
>ADD>							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
	020606	001	LOPERAMIDE HYDROCHLORIDE;IMODIUM ADVANCED	5716641	MAY 21, 2012			
>ADD>	020803	001	LOTEPREDNOL ETABONATE;ALREX				NCE	MAR 09, 2003
>ADD>	020583	001	LOTEPREDNOL ETABONATE;LOTEMAX				NCE	MAR 09, 2003
>ADD>	020841	001	LOTEPREDNOL ETABONATE;LOTEMAX				NCE	MAR 09, 2003
>ADD>	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>	020555	001	NIZATIDINE;AXID AR				I-220	APR 01, 2001
>ADD>							D-39	APR 01, 2001
>ADD>	020799	001	OFLOXACIN;FLOXIN				NDF	DEC 16, 2000
	020237	001	PILOCARPINE HYDROCHLORIDE;SALAGEN				ODE	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		
>ADD>	020835	001	RISEDRONATE SODIUM;ACTONEL				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				NCE	MAR 27, 2003
>ADD>	020895	002	SILDENAFIL CITRATE;VIAGRA				NCE	MAR 27, 2003
>ADD>	020895	003	SILDENAFIL CITRATE;VIAGRA				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
	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		

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
	020697	002	TOLCAPONE;TASMAR	5236952	AUG 17, 2010		NCE	JAN 29, 2003
				5476875	DEC 19, 2012	U-219		
>ADD>	020771	001	TOLTERODINE TARTRATE;DETROL				NCE	MAR 25, 2003
>ADD>	020771	002	TOLTERODINE TARTRATE;DETROL				NCE	MAR 25, 2003
>ADD>	020137	002	TORSEMIDE;DEMADEX				D-38	FEB 13, 2001

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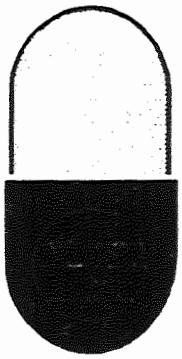

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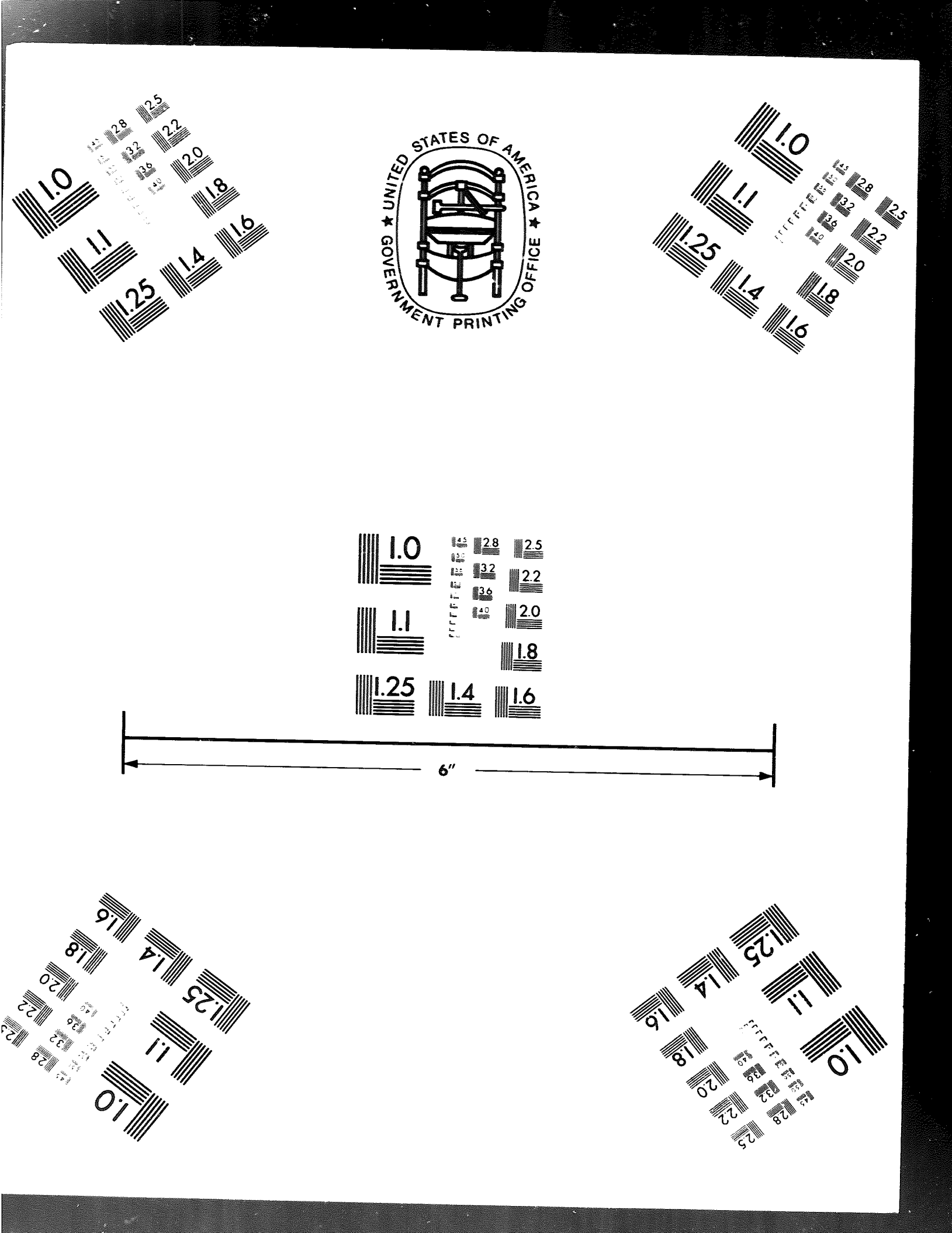
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