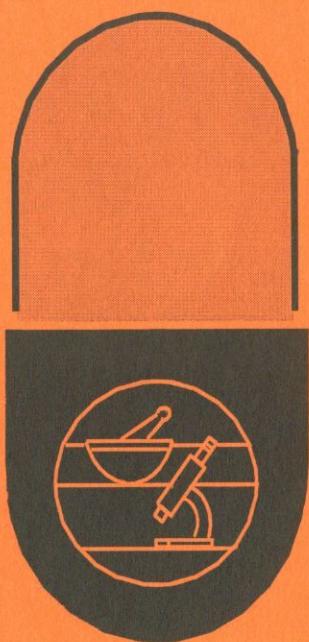


CUMULATIVE
SUPPLEMENT 2
FEBRUARY 2001



APPROVED
DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

21ST EDITION

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

2001

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2001
Feb.
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Prepared By
Division of Data Management and Services
Office of Information Technology
Center for Drug Evaluation and Research
Food and Drug Administration

PAT

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

21ST EDITION

Cumulative Supplement 2

February 2001

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

21ST EDITION

**CUMULATIVE SUPPLEMENT 2
FEBRUARY 2001**

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, 21st 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

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.)

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 21st Edition List will then be added to the "Discontinued Drug Product List" appearing in the 22nd Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

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

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

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >D> (DELETE) to the left of the line. The information line with the >D> symbol is dropped in subsequent Cumulative Supplements for that item.

1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated

Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

APPLICANT NAME CHANGES

<u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u>
NOVOPHARM LTD (NOVOPHARM)	TEVA PHARMACEUTICALS USA (TEVA)
NOVOPHARM PHARMACEUTICAL CO (NOVOPHARM PHARM)	TEVA PHARMACEUTICALS USA (TEVA)
NOVOPHARM NC INC (NOVOPHARM NC)	TEVA PHARMACEUTICALS USA (TEVA)

1.3 AVAILABILITY OF THE EDITION

The 21st Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

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

The telephone number to charge your subscription is 202-512-1800. The cost is \$101.00 annually.

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

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

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

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

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

The 21st annual edition of the 2000 Orange Book Patent and Exclusivity List is at
<http://www.fda.gov/cder/orange/21bookpub.pdf>.

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

The Patent Term Extension and new Patents, Docket Number *95S-0117, is at
<http://www.fda.gov/cder/orange/docket.pdf>. It is updated monthly as soon as available and as otherwise needed.

The Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:

<http://www.fda.gov/cder/orange/patdecl.pdf>
<http://www.fda.gov/cder/orange/patdecl.html>

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

1.4 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 2000) 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

<u>CATEGORIES COUNTED</u>	<u>DEC 2000</u>	<u>MAR 2001</u>	<u>JUN 2001</u>	<u>SEP 2001</u>
DRUG PRODUCTS LISTED	10360			
SINGLE SOURCE	2682 (25.9%)			
MULTISOURCE	7568 (73.1%)			
THERAPEUTICALLY EQUIVALENT	7257 (70.0%)			
NOT THERAPEUTICALLY EQUIVALENT	311 (3.0%)			
EXCEPTIONS ¹	110 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	2			
NUMBER OF APPLICANTS	594			

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

Please Note

1.5 CUMULATIVE SUPPLEMENT LEGEND

The 21st Edition Orange book (OB) Cumulative Supplement (CS) layout has changed. The new format follows the Annual Edition and previous CS format. The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form;Route and then by trade name. The manner of displaying the individual product information has changed.

The individual product record follows the previous format layout for Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Approval number, product number, and approval date. Two new columns have been added to provide more information. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form;route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be proceeded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.
CTNA	Change. Trade Name.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
WDRP	Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition.

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL
>D> TRIAPRIN
>D> DUNHALL 325MG;50MG N89268 001 JUL 02, 1987 FEB WDRP
>A> @ 325MG;50MG N89268 001 JUL 02, 1987 FEB WDRP

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL
>D> ANOQUAN
>D> AB ROBERTS AND HAUCK 325MG;50MG;40MG N87628 001 OCT 01, 1986 FEB WDRP
>A> @ 325MG;50MG;40MG N87628 001 OCT 01, 1986 FEB WDRP

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

TABLET; ORAL
ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE
+ MIKART 712.8MG;60MG;32MG N40316 001 APR 28, 1999 JAN CTNA

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
>D> CAPITAL WITH CODEINE
>D> + CARNICK 325MG;30MG N83643 001 MAY 31, 1974 FEB WDRP
>A> @ 325MG;30MG N83643 001 MAY 31, 1974 FEB WDRP

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
LORTAB
AA + WATSON LABS 325MG;5MG N40099 001 JUN 25, 1997 JAN CAHN

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
>A> AB MALLINCKRODT 650MG;100MG N75738 001 FEB 02, 2001 FEB NEWA
>A> AB VINTAGE PHARMS 325MG;50MG N74843 002 FEB 15, 2001 FEB NEWA

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE
>A> AN ROXANE EQ 0.083% BASE N75129 001 FEB 13, 2001 FEB NEWA

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
AMIODARONE HCL
AB BARR 200MG N75389 001 JAN 25, 2001 JAN NEWA

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN
>D> AB LABS ATRAL 250MG N62528 001 AUG 07, 1985 FEB WDRP
>D> AB 500MG N62528 002 AUG 07, 1985 FEB WDRP
>A> @ 250MG N62528 001 AUG 07, 1985 FEB WDRP
>A> @ 500MG N62528 002 AUG 07, 1985 FEB WDRP

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION

AMPHOTEC

>D>	+	ALZA	50MG/VIAL	N50729 001	NOV 22, 1996	FEB	CAHN
>D>	+		100MG/VIAL	N50729 002	NOV 22, 1996	FEB	CAHN
>A>	+	INTERMUNE PHARMS	50MG/VIAL	N50729 001	NOV 22, 1996	FEB	CAHN
>A>	+		100MG/VIAL	N50729 002	NOV 22, 1996	FEB	CAHN

AMPICILLIN/AMPICILLIN TRIHYDRATE

FOR SUSPENSION; ORAL

>D>		TOTACILLIN					
>D>	AB	SMITHKLINE BEECHAM	EQ 125MG BASE/5ML	N60666 001	MAY 07, 1970	FEB	WDRP
>D>	AB		EQ 250MG BASE/5ML	N60666 002	MAY 07, 1970	FEB	WDRP
>A>	@		EQ 125MG BASE/5ML	N60666 001	MAY 07, 1970	FEB	WDRP
>A>	@		EQ 250MG BASE/5ML	N60666 002	MAY 07, 1970	FEB	WDRP

>A> ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K

>A> INJECTABLE; IV (INFUSION)

>A> INFUVITE PEDIATRIC

>A>	+	SABEX	80MG;0.02MG;400 IU;0.001MG; 5MG;0.14MG;17MG;1MG;1.4MG; 1.2MG;7 IU;2,300 IU;0.2MG (ALL POTENCIES PER VIAL)	N21265 001	FEB 21, 2001	FEB	NEWA
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ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

>A> FOR SOLUTION; IV (INFUSION)

>A> M.V.I. PEDIATRIC

>A>	+	ASTRAZENECA	80MG/VIAL;0.02MG/VIAL; 0.001MG/VIAL;5MG/VIAL;0.01MG/VIAL; 0.14MG/VIAL;17MG/VIAL; 0.2MG/VIAL;EQ 1MG BASE/VIAL; 1.4MG/VIAL;EQ1.2MG BASE/VIAL; 0.7MG/VIAL	N18920 001	SEP 21, 2000	FEB	NEWA
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ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

INVAGESIC

AB	GENEVA PHARMS TECH	385MG;30MG;25MG	N74817 001	NOV 27, 1996	JAN	CAHN
	INVAGESIC FORTE					
AB	GENEVA PHARMS TECH	770MG;60MG;50MG	N74817 002	NOV 27, 1996	JAN	CAHN

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

>D>	AA	INWOOD LABS	0.025MG;2.5MG	N85509 001	MAR 09, 1978	FEB	WDRP
>A>	@		0.025MG;2.5MG	N85509 001	MAR 09, 1978	FEB	WDRP

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE
OINTMENT; OPHTHALMIC

>D>	NEO-POLYCIN				
>D>	DOW PHARM	500 UNITS/GM;EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N60647 001	APR 19, 1954	FEB WDRP
>A>	⑧	500 UNITS/GM;EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N60647 001	APR 19, 1954	FEB WDRP

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL					
BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE					
AB	TEVA	2.5MG;6.25MG	N75686 001	JAN 19, 2001	JAN NEWA
AB		5MG;6.25MG	N75686 002	JAN 19, 2001	JAN NEWA
AB		10MG;6.25MG	N75686 003	JAN 19, 2001	JAN NEWA

CAPTOPRIL

TABLET; ORAL					
Captopril					
AB	GENEVA PHARMS TECH	12.5MG	N74481 001	FEB 13, 1996	JAN CAHN
AB		25MG	N74481 002	FEB 13, 1996	JAN CAHN
AB		50MG	N74481 003	FEB 13, 1996	JAN CAHN
AB		100MG	N74481 004	FEB 13, 1996	JAN CAHN

CARBACHOL

SOLUTION; INTRAOCULAR						
CARBASTAT						
>D>	AT	CIBA	0.01%	N73677 001	APR 28, 1995	FEB CAHN
>A>	AT	NOVARTIS	0.01%	N73677 001	APR 28, 1995	FEB CAHN

CARBIDOPA; LEVODOPA

TABLET; ORAL						
CARBIDOPA AND LEVODOPA						
>D>	AB	SCS	10MG;100MG	N74080 001	MAR 25, 1994	FEB WDRP
>D>	AB		25MG;100MG	N74080 002	MAR 25, 1994	FEB WDRP
>D>	AB		25MG;250MG	N74080 003	MAR 25, 1994	FEB WDRP
>A>	⑧		10MG;100MG	N74080 001	MAR 25, 1994	FEB WDRP
>A>	⑧		25MG;100MG	N74080 002	MAR 25, 1994	FEB WDRP
>A>	⑧		25MG;250MG	N74080 003	MAR 25, 1994	FEB WDRP

CASPOFUNGIN ACETATE

INJECTABLE; IV (INFUSION)					
CANCIDAS					
+	MERCK RES	50MG/VIAL	N21227 001	JAN 26, 2001	JAN NEWA
+		70MG/VIAL	N21227 002	JAN 26, 2001	JAN NEWA

CEFACLOR

TABLET, EXTENDED RELEASE; ORAL						
CECLOR CD						
AB	+	LILLY	EQ 500MG BASE	N50673 002	JUN 28, 1996	JAN CFTG
CEFACLOR						
AB		ZENITH GOLDLINE	EQ 500MG BASE	N65057 001	JAN 05, 2001	JAN NEWA

CEFTAZIDIME

INJECTABLE; INJECTION

TAZICEF

AP	ABBOTT	500MG/VIAL	N62662 001	MAR 06, 1986	JAN CAHN
AP		1GM/VIAL	N62662 002	MAR 06, 1986	JAN CAHN
AP		1GM/VIAL	N64032 001	OCT 31, 1993	JAN CAHN
AP		2GM/VIAL	N62662 003	MAR 06, 1986	JAN CAHN
AP		2GM/VIAL	N64032 002	OCT 31, 1993	JAN CAHN
AP		6GM/VIAL	N62662 004	MAR 06, 1986	JAN CAHN

CEFURONIUM CHLORIDE

INJECTABLE; INJECTION

>A>	CEFURONIUM AND DEXTROSE IN DUPLEX CONTAINER				
>A>	+	B BRAUN	EQ 15MG BASE/ML	N50780 001	FEB 21, 2001 FEB NEWA
>A>	+		EQ 30MG BASE/M	N50780 002	FEB 21, 2001 FEB NEWA

CHLORAMPHENICOL

SOLUTION/DROPS; OPHTHALMIC

CHLORAMPHENICOL

>D>	AT	AKORN	0.5%	N62042 001	AUG 31, 1981 FEB WDRP
>A>		@	0.5%	N62042 001	AUG 31, 1981 FEB WDRP

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZACHEL

>D>	AB	RACHELLE	5MG	N85086 001	MAY 11, 1976 FEB WDRP
>D>	AB		10MG	N84639 001	MAY 11, 1976 FEB WDRP
>D>	AB		25MG	N85087 001	MAY 11, 1976 FEB WDRP
>A>		@	5MG	N85086 001	MAY 11, 1976 FEB WDRP
>A>		@	10MG	N84639 001	MAY 11, 1976 FEB WDRP
>A>		@	25MG	N85087 001	MAY 11, 1976 FEB WDRP
	CHLORDIAZEPOXIDE HCL				
>D>	AB	FERRANTE	5MG	N85118 001	SEP 02, 1981 FEB WDRP
>D>	AB		10MG	N85119 001	SEP 02, 1976 FEB WDRP
>D>	AB		25MG	N85120 001	SEP 02, 1976 FEB WDRP
>A>		@	5MG	N85118 001	SEP 02, 1981 FEB WDRP
>A>		@	10MG	N85119 001	SEP 02, 1976 FEB WDRP
>A>		@	25MG	N85120 001	SEP 02, 1976 FEB WDRP

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

>D>	AA	PHARMAVITE	4MG	N85104 001	FEB 11, 1977 FEB WDRP
>A>		@	4MG	N85104 001	FEB 11, 1977 FEB WDRP
>D>	AA	WEST WARD	4MG	N83787 001	OCT 18, 1973 FEB WDRP
>A>		@	4MG	N83787 001	OCT 18, 1973 FEB WDRP

CIMETIDINE

TABLET; ORAL

CIMETIDINE

AB	GENEVA PHARMS TECH	200MG	N74506 001	JAN 24, 1996 JAN CAHN
AB		300MG	N74506 002	JAN 24, 1996 JAN CAHN

AB	400MG	N74506 003	JAN 24, 1996	JAN	CAHN
AB	800MG	N74506 004	JAN 24, 1996	JAN	CAHN

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLEOCIN HCL

>A>	AB + PHARMACIA AND UPJOHN	EQ 300MG BASE	N50162 003	APR 14, 1988	FEB	CFTG
>D>	+ CLINDAMYCIN HCL	EQ 300MG BASE	N50162 003	APR 14, 1988	FEB	CFTG
>A>	AB RANBAXY	EQ 150MG BASE	N65061 001	FEB 02, 2001	FEB	NEWA
>A>	AB	EQ 300MG BASE	N65061 002	FEB 02, 2001	FEB	NEWA

CLOBETASOL PROPIONATE

CREAM; TOPICAL

CLOBETASOL PROPIONATE

>A>	AB1 STIEFEL	0.05%	N75338 001	FEB 09, 2001	FEB	NEWA
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CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

@ ABLE	3.75MG	N71777 001	JUL 14, 1987	JAN	DISC
@	7.5MG	N71778 001	JUL 14, 1987	JAN	DISC
@	15MG	N71779 001	JUL 14, 1987	JAN	DISC

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC

CROMOLYN SODIUM

AT NOVEX	4%	N75615 001	JAN 26, 2001	JAN	NEWA
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DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

>D>	AP DELL LABS	EQ 4MG PHOSPHATE/ML	N83161 001	JUN 06, 1978	FEB	WDRP
>A>	@	EQ 4MG PHOSPHATE/ML	N83161 001	JUN 06, 1978	FEB	WDRP
>D>	SOLUTION/DROPS; OTIC					
>D>	DEXAMETHASONE SODIUM PHOSPHATE					
>D>	AT AKORN	EQ 0.1% PHOSPHATE	N84855 001	JUN 29, 1976	FEB	WDRP
>A>	@	EQ 0.1% PHOSPHATE	N84855 001	JUN 29, 1976	FEB	WDRP

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

DEXACIDIN

>D>	AT CIBA	0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N62566 001	FEB 22, 1985	FEB	CAHN
>A>	AT NOVARTIS	0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N62566 001	FEB 22, 1985	FEB	CAHN

SUSPENSION/DROPS; OPHTHALMIC

>D>	AT CIBA	0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N62544 001	OCT 29, 1984	FEB	CAHN
>A>	AT	0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N62544 001	OCT 29, 1984	FEB	CAHN

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DEXTROAMPHETAMINE SULFATE

AA BARR	5MG	N40361 001	JAN 31, 2001	JAN	NEWA
AA	10MG	N40361 002	JAN 31, 2001	JAN	NEWA

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DEXTROSTAT

AA + SHIRE RICHWOOD

10MG

N84051 002 MAY 29, 1975 JAN CFTG

DICLOFENAC POTASSIUM

TABLET; ORAL

DICLOFENAC POTASSIUM

>A> AB EON 50MG N75582 001 FEB 23, 2001 FEB NEWA

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

>D>	AA	NEWTRON PHARMS	25MG	N86543 001 FEB 08, 1979 FEB WDRP
>D>	AA		50MG	N86544 001 FEB 08, 1979 FEB WDRP
>A>	@		25MG	N86543 001 FEB 08, 1979 FEB WDRP
>A>	@		50MG	N86544 001 FEB 08, 1979 FEB WDRP

DISULFIRAM

TABLET; ORAL

ANTABUSE

ODYSSEY PHARMS

+

250MG

N88482 001 DEC 08, 1983 JAN CAHN

500MG

N88483 001 DEC 08, 1983 JAN CAHN

DOXAZOSIN MESYLATE

TABLET; ORAL

DOXAZOSIN MESYLATE

AB	TEVA	EQ 1MG BASE	N75353 001 JAN 12, 2001 JAN NEWA
AB		EQ 2MG BASE	N75353 002 JAN 12, 2001 JAN NEWA
AB		EQ 4MG BASE	N75353 003 JAN 12, 2001 JAN NEWA
AB		EQ 8MG BASE	N75353 004 JAN 12, 2001 JAN NEWA

DOXYCYCLINE

FOR SUSPENSION; ORAL

DOXYCHEL

>D>	AB	RACHELLE	EQ 25MG BASE/5ML	N61720 001 JUN 18, 1973 FEB WDRP
>A>	@		EQ 25MG BASE/5ML	N61720 001 JUN 18, 1973 FEB WDRP
VIBRAMYCIN				
>D>	AB	+ PFIZER	EQ 25MG BASE/5ML	N50006 001 DEC 06, 1967 FEB CTEC
>A>	+		EQ 25MG BASE/5ML	N50006 001 DEC 06, 1967 FEB CTEC

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

DOXYCHEL HYCLATE

>D>	AP	RACHELLE	EQ 100MG BASE/VIAL	N61953 001 SEP 10, 1980 FEB WDRP
>A>	@		EQ 100MG BASE/VIAL	N61953 001 SEP 10, 1980 FEB WDRP
TABLET; ORAL				
>A>		PERIOSTAT		
>A>	+	COLLAGENEX PHARMS	20MG	N50783 001 FEB 02, 2001 FEB NEWA

ENALAPRIL MALEATE

TABLET; ORAL

ENALAPRIL MALEATE

AB	TARO	2.5MG	N75657 001	JAN 23, 2001	JAN NEWA
AB		5MG	N75657 002	JAN 23, 2001	JAN NEWA
AB		10MG	N75657 003	JAN 23, 2001	JAN NEWA
AB		20MG	N75657 004	JAN 23, 2001	JAN NEWA

ENFLURANE

LIQUID; INHALATION

ENFLURANE

>D>	AN	MINRAD	99.9%	N74396 001	JUL 29, 1994	FEB CAHN
>A>	AN		99.9%	N74396 001	JUL 29, 1994	FEB CAHN

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCATON

>D>	AP	PHARMATON	0.02MG/ML;2%	N84728 001	AUG 17, 1983	FEB WDRP
>A>		@	0.02MG/ML;2%	N84728 001	AUG 17, 1983	FEB WDRP

ERGOCALCIFEROL

CAPSULE; ORAL

VITAMIN D

>D>	AA	IMPAK LABS	50,000 IU	N80951 001	JUL 13, 1973	FEB DISC
>A>		@	50,000 IU	N80951 001	JUL 13, 1973	FEB DISC

>A> ESOMEPRAZOLE MAGNESIUM

>A> CAPSULE, DELAYED REL PELLETS; ORAL

>A> NEXIUM

>A> + ASTRazeneca EQ 20MG BASE

>A> + EQ 40MG BASE

N21153 001 FEB 20, 2001 FEB NEWA

N21153 002 FEB 20, 2001 FEB NEWA

ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE

TABLET; ORAL-28

PREMPRO

+ WYETH AYERST 0.625MG,0.625MG;2.5MG,2.5MG

N20527 001 NOV 17, 1995 JAN CTNA

+ 0.625MG,0.625MG;5MG,5MG

N20527 003 JAN 09, 1998 JAN CTNA

PREMPRO (PREMARIN;CYCRIN)

+ WYETH AYERST

0.625MG,0.625MG;2.5MG,2.5MG

N20303 001 DEC 30, 1994 JAN CTNA

ESTROPIRATE

TABLET; ORAL

ORTHO-EST

AB WOMEN FIRST HLTHCARE 0.75MG

N89567 001 FEB 27, 1991 JAN CAHN

AB 1.5MG

N89582 001 JUL 17, 1991 JAN CAHN

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-28

>A> LOESTRIN FE 1.5/30

>A> AB + PARKE DAVIS 0.03MG;1.5MG

N17355 001 APR 30, 1973 FEB CFTG

>D>	+	0.03MG;1.5MG	N17355 001	APR 30, 1973	FEB	CFTG
>A>	LOESTRIN FE 1/20					
>A>	AB + PARKE DAVIS	0.02MG;1MG	N17354 001	APR 30, 1973	FEB	CFTG
>D>	+	0.02MG;1MG	N17354 001	APR 30, 1973	FEB	CFTG
>A>	MICROGESTIN FE 1.5/30					
>A>	AB WATSON LABS	0.03MG;1.5MG	N75548 001	FEB 05, 2001	FEB	NEWA
>A>	MICROGESTIN FE 1/20					
>A>	AB WATSON LABS	0.02MG;1MG	N75647 001	FEB 05, 2001	FEB	NEWA

ETHOSUXIMIDE

SYRUP; ORAL

ZARONTIN

AA + PARKE DAVIS	250MG/5ML	N80258 001	FEB 13, 1974	JAN	CRLD
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ETODOLAC

TABLET, EXTENDED RELEASE; ORAL

ETODOLAC

>A> AB TEVA	400MG	N75665 003	FEB 05, 2001	FEB	NEWA
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FAMCICLOVIR

TABLET; ORAL

FAMVIR

NOVARTIS	125MG	N20363 003	DEC 11, 1995	JAN	CAHN
	250MG	N20363 001	APR 26, 1996	JAN	CAHN
+	500MG	N20363 002	JUN 29, 1994	JAN	CAHN

FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE PRESERVATIVE FREE

@ MARSAM	EQ 0.05MG BASE/ML	N74917 001	FEB 03, 1998	JAN	DISC
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FLOXURIDINE

INJECTABLE; INJECTION

FLOXURIDINE

>A> AP AM PHARM PARTNERS	500MG/VIAL	N75837 001	FEB 22, 2001	FEB	NEWA
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FLUOROMETHOLONE

SUSPENSION; OPHTHALMIC

FLUOR-OP

>D> AB CIBA	0.1%	N70185 001	FEB 27, 1986	FEB	CAHN
>A> AB NOVARTIS	0.1%	N70185 001	FEB 27, 1986	FEB	CAHN

FLUOXETINE HYDROCHLORIDE

>A> CAPSULE, DELAYED REL PELLETS; ORAL					
>A> PROZAC WEEKLY					
>A> + LILLY	EQ 90MG BASE	N21235 001	FEB 26, 2001	FEB	NEWA

FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

AB BARR	25MG	N75897 001	JAN 25, 2001	JAN	NEWA
AB	50MG	N75897 002	JAN 25, 2001	JAN	NEWA
AB	100MG	N75897 003	JAN 25, 2001	JAN	NEWA

AB	INVAMED	25MG	N75887 001	JAN 05, 2001	JAN NEWA
AB		50MG	N75887 002	JAN 05, 2001	JAN NEWA
AB		100MG	N75887 003	JAN 05, 2001	JAN NEWA
AB	SYNTON PHARMS	25MG	N75899 001	JAN 17, 2001	JAN NEWA
AB		50MG	N75899 002	JAN 17, 2001	JAN NEWA
AB		100MG	N75899 003	JAN 17, 2001	JAN NEWA
>A>	<u>FORMOTEROL FUMARATE</u>				
>A>	CAPSULE; INHALATION				
>A>	FORADIL				
>A>	+ NOVARTIS	0.012MG/INH	N20831 001	FEB 16, 2001	FEB NEWA
>A>	<u>GALANTAMINE HYDROBROMIDE</u>				
>A>	TABLET; ORAL				
>A>	REMINYL				
>A>	JANSSEN RES FDN	EQ 4MG BASE	N21169 001	FEB 28, 2001	FEB NEWA
>A>		EQ 8MG BASE	N21169 002	FEB 28, 2001	FEB NEWA
>A>	+	EQ 12MG BASE	N21169 003	FEB 28, 2001	FEB NEWA
	<u>GEMFIBROZIL</u>				
	TABLET; ORAL				
	GEMFIBROZIL				
AB	GENEVA PHARMS TECH	600MG	N74615 001	SEP 29, 1995	JAN CAHN
	<u>GENTAMICIN SULFATE</u>				
	INJECTABLE; INJECTION				
>D>	U-GENCIN				
>D>	AP PHARMACIA AND UPJOHN	EQ 10MG BASE/ML	N62248 001	MAY 02, 1980	FEB WDRP
>D>	AP	EQ 40MG BASE/ML	N62248 002	MAY 02, 1980	FEB WDRP
>A>	@	EQ 10MG BASE/ML	N62248 001	MAY 02, 1980	FEB WDRP
>A>	@	EQ 40MG BASE/ML	N62248 002	MAY 02, 1980	FEB WDRP
	OINTMENT; OPHTHALMIC				
	GENTACIDIN				
>D>	AT CIBA	EQ 0.3% BASE	N62501 001	JUL 26, 1984	FEB CAHN
>A>	AT NOVARTIS	EQ 0.3% BASE	N62501 001	JUL 26, 1984	FEB CAHN
	SOLUTION/DROPS; OPHTHALMIC				
	GENTACIDIN				
>D>	AT CIBA	EQ 0.3% BASE	N62480 001	MAR 30, 1984	FEB CAHN
>A>	AT NOVARTIS	EQ 0.3% BASE	N62480 001	MAR 30, 1984	FEB CAHN
	<u>GLIPIZIDE</u>				
	TABLET; ORAL				
	GLIPIZIDE				
AB	GENEVA PHARMS TECH	5MG	N74542 001	JUN 20, 1995	JAN CAHN
AB		10MG	N74542 002	JUN 20, 1995	JAN CAHN
	<u>HALOTHANE</u>				
	LIQUID; INHALATION				
	HALOTHANE				
	@ BH	99.99%	N84977 001	JUL 14, 1976	JAN DISC

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM PRESERVATIVE FREE

>D>	AP	PHARMA SERVE NY	1,000 UNITS/ML	N86129 001	FEB 22, 1980	FEB	WDRP
>A>	⑧		1,000 UNITS/ML	N86129 001	FEB 22, 1980	FEB	WDRP

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

>D>		RESERPINE AND HYDROCHLOROTHIAZIDE-50					
>D>	BP	WEST WARD	50MG;0.125MG	N88189 001	MAY 10, 1984	FEB	WDRP
>A>	⑧		50MG;0.125MG	N88189 001	MAY 10, 1984	FEB	WDRP

HYDROCORTISONE

CREAM; TOPICAL

>D>		HC (HYDROCORTISONE)					
>D>	AT	C AND M PHARMA	0.5%	N80482 003	MAR 20, 1973	FEB	WDRP
>D>	AT		1%	N80482 004	MAR 20, 1973	FEB	WDRP
>A>	⑧		0.5%	N80482 003	MAR 20, 1973	FEB	WDRP
>A>	⑧		1%	N80482 004	MAR 20, 1973	FEB	WDRP

HYDROCORTISONE

>D>	AT	TOPIDERM	1%	N89273 001	FEB 17, 1989	FEB	WDRP
>A>	⑧		1%	N89273 001	FEB 17, 1989	FEB	WDRP
>D>		PROCTOCORT					
>D>	AT	MONARCH PHARMS	1%	N83011 001	APR 26, 1973	FEB	DISC
>A>	⑧		1%	N83011 001	APR 26, 1973	FEB	DISC

LOTION; TOPICAL

>D>		BETA-HC					
>D>	AT	BETA DERMAC	1%	N89495 001	JAN 25, 1988	FEB	WDRP
>A>	⑧		1%	N89495 001	JAN 25, 1988	FEB	WDRP
>D>		GLYCORT					
>D>	AT	HERAN	1%	N87489 001	OCT 03, 1983	FEB	WDRP
>A>	⑧		1%	N87489 001	OCT 03, 1983	FEB	WDRP

OINTMENT; TOPICAL

>D>		HC (HYDROCORTISONE)					
>D>	AT	C AND M PHARMA	1%	N80481 002	MAR 20, 1973	FEB	WDRP
>A>	⑧		1%	N80481 002	MAR 20, 1973	FEB	WDRP

POWDER; FOR RX COMPOUNDING

>D>		H-CORT					
>D>	AA	TORCH	100%	N87834 001	MAR 29, 1982	FEB	WDRP
>A>	⑧		100%	N87834 001	MAR 29, 1982	FEB	WDRP

HYDROCORTISONE ACETATE

CREAM; TOPICAL

>A>		MICORT-HC					
>A>		FERNDALE LABS	2.5%	N40396 001	FEB 27, 2001	FEB	NEWA

HYDROCORTISONE ACETATE; NEOMYCIN SULFATE

>D>		SUSPENSION/DROPS; OPHTHALMIC					
>D>		COR-OTICIN					
>D>	+	AKORN	1.5%;EQ 3.5MG BASE/ML	N60188 001	OCT 26, 1968	FEB	WDRP
>A>	⑧		1.5%;EQ 3.5MG BASE/ML	N60188 001	OCT 26, 1968	FEB	WDRP

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

>D>	AB	VANGARD	EQ 50MG HCL	N88393 001	SEP 19, 1983	FEB	WDRP
>A>		@	EQ 50MG HCL	N88393 001	SEP 19, 1983	FEB	WDRP

INDAPAMIDE

TABLET; ORAL

INDAPAMIDE

AB	GENEVA PHARMS TECH	1.25MG	N74594 001	MAY 23, 1996	JAN	CAHN
AB		2.5MG	N74594 002	MAY 23, 1996	JAN	CAHN

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

AN	ASLUNG PHARM	0.02%	N75693 001	JAN 26, 2001	JAN	NEWA
AN	WARRICK PHARMS	0.02%	N75507 001	JAN 19, 2001	JAN	NEWA

ISOFLURANE

LIQUID; INHALATION

ISOFLURANE

>D>	AN	MINRAD	99.9%	N74416 001	SEP 30, 1994	FEB	CAHN
>A>	AN		99.9%	N74416 001	SEP 30, 1994	FEB	CAHN

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM PRESERVATIVE FREE

AP	LUITPOLD	EQ 50MG BASE/VIAL	N40338 001	JAN 31, 2001	JAN	NEWA
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LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCATON

>D>	AP	PHARMATON	2%	N84727 001	AUG 17, 1983	FEB	WDRP
>A>		@	2%	N84727 001	AUG 17, 1983	FEB	WDRP

MEPROBAMATE

TABLET; ORAL

AMOSENE

>D>	AA	FERNDALE LABS	400MG	N84030 001	MAY 10, 1974	FEB	WDRP
>A>			400MG	N84030 001	MAY 10, 1974	FEB	WDRP

MESALAMINE

SUPPOSITORY; RECTAL

CANASA

+ AXCAN SCANDIPHARM

500MG

N21252 001 JAN 05, 2001 JAN NEWA

METAPROTERENOL SULFATE

SOLUTION; INHALATION

METAPROTERENOL SULFATE

>A>	AN	NOVEX	0.4%	N75402 001	FEB 28, 2001	FEB	NEWA
>A>	AN		0.6%	N75403 001	FEB 28, 2001	FEB	NEWA

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
METHYLPHENIDATE HCL

>A> AB DANBURY PHARMA 20MG N40410 001 FEB 09, 2001 FEB NEWA

METHYLTESTOSTERONE

TABLET; BUCCAL
ORETON

>D> + SCHERING 10MG N80281 001 AUG 03, 1979 FEB DISC
>A> @ 10MG N80281 001 AUG 03, 1979 FEB DISC

METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION; INJECTION
METOCLOPRAMIDE

AA UDL EQ 5MG BASE/5ML N75051 001 JAN 26, 2001 JAN NEWA
TABLET; ORAL
METOCLOPRAMIDE HCL
AB GENEVA PHARMS TECH EQ 5MG BASE N74478 001 OCT 05, 1995 JAN CAHN
AB EQ 10MG BASE N74478 002 OCT 05, 1995 JAN CAHN

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL
TOPROL-XL

>A> + ASTRAZENECA EQ 25MG TARTRATE N19962 004 FEB 05, 2001 FEB NEWA

MINOCYCLINE HYDROCHLORIDE

>A> POWDER, EXTENDED RELEASE; DENTAL
>A> ARRESTIN
>A> + EQ 1MG BASE N50781 001 FEB 16, 2001 FEB NEWA

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL
REMERON SOLTAB

+ ORGANON INC 15MG N21208 001 JAN 12, 2001 JAN NEWA
30MG N21208 002 JAN 12, 2001 JAN NEWA
45MG N21208 003 JAN 12, 2001 JAN NEWA

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE

AB WATSON LABS 100MG N75656 001 JAN 30, 2001 JAN NEWA

NADOLOL

TABLET; ORAL
NADOLOL

AB GENEVA PHARMS TECH 20MG N74501 001 NOV 09, 1995 JAN CAHN
AB 40MG N74501 002 NOV 09, 1995 JAN CAHN
AB 80MG N74501 003 NOV 09, 1995 JAN CAHN

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE

@ WYETH AYERST	0.02MG/ML	N70188 001	SEP 24, 1986	JAN	DISC
@	0.02MG/ML	N70189 001	SEP 24, 1986	JAN	DISC
@	0.4MG/ML	N70190 001	SEP 24, 1986	JAN	DISC
@	0.4MG/ML	N70191 001	SEP 24, 1986	JAN	DISC

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

VASOCON

>D> AT	CIBA	0.1%	N80235 002	MAR 24, 1983	FEB	CAHN
>A> AT	NOVARTIS	0.1%	N80235 002	MAR 24, 1983	FEB	CAHN

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

AB	GENEVA PHARMS TECH	EQ 250MG BASE	N74495 001	DEC 05, 1994	JAN	CAHN
AB		EQ 500MG BASE	N74495 002	DEC 05, 1994	JAN	CAHN

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

>D> AB	CHASE LABS NJ	10MG	N72409 001	JUL 04, 1990	FEB	WDRP
>D> AB		20MG	N73421 001	JUN 19, 1991	FEB	WDRP
>A>	@	10MG	N72409 001	JUL 04, 1990	FEB	WDRP
>A>	@	20MG	N73421 001	JUN 19, 1991	FEB	WDRP
	TABLET, EXTENDED RELEASE; ORAL					
>A> AB2	BIOVAIL	30MG	N75289 002	FEB 06, 2001	FEB	NEWA
	PROCARDIA XL					
>A> AB2 +	PFIZER	30MG	N19684 001	SEP 06, 1989	FEB	CTEC
>D> BC +		30MG	N19684 001	SEP 06, 1989	FEB	CTEC

NITROFURAZONE

POWDER; TOPICAL

FURACIN

>D>	ROBERTS LABS	0.2%	N83791 001	OCT 17, 1975	FEB	WDRP
>A>	@	0.2%	N83791 001	OCT 17, 1975	FEB	WDRP

NYSTATIN

TABLET; VAGINAL

>D>	KOROSTATIN					
>D> AT	HOLLAND RANTOS	100,000 UNITS	N61718 001	SEP 30, 1974	FEB	WDRP
>A>	@	100,000 UNITS	N61718 001	SEP 30, 1974	FEB	WDRP

OXACILLIN SODIUM

INJECTABLE; INJECTION

BACTOCILL

>D>	SMITHKLINE BEECHAM	EQ 1GM BASE/VIAL	N62736 001	DEC 19, 1986	FEB	DISC
>D>	AP +	EQ 2GM BASE/VIAL	N62736 002	DEC 19, 1986	FEB	DISC
>A>	@	EQ 1GM BASE/VIAL	N62736 001	DEC 19, 1986	FEB	DISC
>A>	@	EQ 2GM BASE/VIAL	N62736 002	DEC 19, 1986	FEB	DISC

OXACILLIN SODIUMINJECTABLE; INJECTION
OXACILLIN SODIUM

>D>	AP	APOTHECON	EQ 1GM BASE/VIAL	N61490 003	APR 08, 1971	FEB	CRLD
>A>	AP	+	EQ 1GM BASE/VIAL	N61490 003	APR 08, 1971	FEB	CRLD
>D>	AP		EQ 2GM BASE/VIAL	N62737 002	DEC 23, 1986	FEB	CRLD
>A>	AP	+	EQ 2GM BASE/VIAL	N62737 002	DEC 23, 1986	FEB	CRLD

OXaprozinTABLET; ORAL
DAYPRO

AB	+	SEARLE	600MG	N18841 004	OCT 29, 1992	JAN	CFTG
		OXaprozin					
AB		DR REDDYS LABS LTD	600MG	N75855 001	JAN 31, 2001	JAN	NEWA
AB		EON	600MG	N75845 001	JAN 31, 2001	JAN	NEWA
>A>	AB	GENPHARM	600MG	N75847 001	FEB 28, 2001	FEB	NEWA
>A>	AB	WATSON LABS	600MG	N75848 001	FEB 09, 2001	FEB	NEWA

OXYTETRACYCLINE HYDROCHLORIDECAPSULE; ORAL
OXYTETRACYCLINE HCL

>D>	AB	IMPAK LABS	EQ 250MG BASE	N60760 001	AUG 09, 1967	FEB	DISC
>A>		⑧	EQ 250MG BASE	N60760 001	AUG 09, 1967	FEB	DISC
>D>	AB	PROTER	EQ 250MG BASE	N60869 001	JAN 29, 1964	FEB	WDRP
>A>		⑧	EQ 250MG BASE	N60869 001	JAN 29, 1964	FEB	WDRP

PENICILLIN G SODIUMINJECTABLE; IM-IV
PENICILLIN G SODIUM

>A>	+	BIOCHEMIE	5,000,000 UNITS/VIALS	N65068 001	FEB 26, 2001	FEB	NEWA
>D>	+	MARSAM	5,000,000 UNITS/VIALS	N63014 001	SEP 13, 1988	FEB	DISC
>A>	⑧		5,000,000 UNITS/VIALS	N63014 001	SEP 13, 1988	FEB	DISC

PHENYTOINSUSPENSION; ORAL
PHENYTOIN

AB		UDL	125MG/5ML	N40342 001	JAN 31, 2001	JAN	NEWA
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PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

OINTMENT; OPHTHALMIC

VASOCIDIN

>D>	AT	CIBA	0.5%;10%	N88791 001	OCT 05, 1984	FEB	CAHN
>A>	AT	NOVARTIS	0.5%;10%	N88791 001	OCT 05, 1984	FEB	CAHN
		SUSPENSION/DROPS; OPHTHALMIC					
		METIMYD					
>D>	AT	+ SCHERING	0.5%;10%	N10210 001	FEB 24, 1956	FEB	CTEC
>A>		+	0.5%;10%	N10210 001	FEB 24, 1956	FEB	CTEC
>D>		PREDAMIDE					
>D>	AT	AKORN	0.5%;10%	N88059 001	JUL 29, 1983	FEB	WDRP
>A>		⑧	0.5%;10%	N88059 001	JUL 29, 1983	FEB	WDRP
>D>		SULPHRIN					
>D>	AT	BAUSCH AND LOMB	0.5%;10%	N88089 001	DEC 28, 1982	FEB	WDRP
>A>		⑧	0.5%;10%	N88089 001	DEC 28, 1982	FEB	WDRP

<u>PREDNISOLONE SODIUM PHOSPHATE</u>									
SOLUTION/DROPS; OPHTHALMIC									
INFLAMASE FORTE									
>D> AT + CIBA EQ 0.9% PHOSPHATE N80751 002 DEC 19, 1973 FEB CAHN									
>A>	AT + NOVARTIS	EQ 0.9% PHOSPHATE	N80751	002	DEC 19, 1973	FEB	CAHN		
INFLAMASE MILD									
>D> AT + CIBA EQ 0.11% PHOSPHATE N80751 001 DEC 19, 1973 FEB CAHN									
>A>	AT + NOVARTIS	EQ 0.11% PHOSPHATE	N80751	001	DEC 19, 1973	FEB	CAHN		
PREDNISOLONE SODIUM PHOSPHATE									
>D> AT AKORN EQ 0.11% PHOSPHATE N83358 001 AUG 21, 1974 FEB WDRP									
>D>	AT	EQ 0.9% PHOSPHATE	N83358	002	AUG 21, 1974	FEB	WDRP		
>A>	⊕	EQ 0.11% PHOSPHATE	N83358	001	AUG 21, 1974	FEB	WDRP		
>A>	⊕	EQ 0.9% PHOSPHATE	N83358	002	AUG 21, 1974	FEB	WDRP		
<u>PROCHLORPERAZINE MALEATE</u>									
TABLET; ORAL									
PROCHLORPERAZINE MALEATE									
AB	GENEVA PHARMS TECH	EQ 5MG BASE	N40101	001	JUL 19, 1996	JAN	CAHN		
AB		EQ 10MG BASE	N40101	002	JUL 19, 1996	JAN	CAHN		
AB		EQ 25MG BASE	N40101	003	JUL 19, 1996	JAN	CAHN		
<u>PROTRIPTYLINE HYDROCHLORIDE</u>									
TABLET; ORAL									
PROTRIPTYLINE HCL									
AB	ODYSSEY PHARMS	5MG	N73644	001	AUG 24, 1995	JAN	CAHN		
AB		10MG	N73645	001	AUG 24, 1995	JAN	CAHN		
<u>PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE</u>									
>D>	SYRUP; ORAL								
>D>	TRILITRON								
>D>	+ NEWTRON PHARMS	30MG/5ML;1.25MG/5ML	N88474	001	FEB 12, 1985	FEB	WDRP		
>A>	⊕	30MG/5ML;1.25MG/5ML	N88474	001	FEB 12, 1985	FEB	WDRP		
<u>QUINIDINE SULFATE</u>									
TABLET; ORAL									
QUINIDINE SULFATE									
>D> AB	IMPAK LABS	200MG	N83347	001	DEC 08, 1976	FEB	DISC		
>A>	⊕	200MG	N83347	001	DEC 08, 1976	FEB	DISC		
<u>SECOBARBITAL SODIUM</u>									
CAPSULE; ORAL									
SECOBARBITAL SODIUM									
>D> AA	ICN	100MG	N85477	001	DEC 10, 1981	FEB	WDRP		
>A>	⊕	100MG	N85477	001	DEC 10, 1981	FEB	WDRP		
<u>SULFACETAMIDE SODIUM</u>									
SOLUTION/DROPS; OPHTHALMIC									
SULF-10									
>D>	⊕ CIBA	10%	N80025	001	JUN 03, 1971	FEB	CAHN		
>A>	⊕ NOVARTIS	10%	N80025	001	JUN 03, 1971	FEB	CAHN		
>D>	SULF-15								
>D> AT	CIBA	15%	N89047	001	OCT 31, 1995	FEB	CAHN		

>A>	AT	NOVARTIS	15%	N89047 001	OCT 31, 1995	FEB	CAHN
>D>		SULTEN-10					
>D>	AT	BAUSCH AND LOMB	10%	N87818 001	FEB 03, 1983	FEB	WDRP
>A>	@		10%	N87818 001	FEB 03, 1983	FEB	WDRP

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

>D>		TRIMETH/SULFA					
>D>	AB	NASKA	200MG/5ML;40MG/5ML	N72399 001	MAY 23, 1988	FEB	WDRP
>A>	@		200MG/5ML;40MG/5ML	N72399 001	MAY 23, 1988	FEB	WDRP

SULFANILAMIDE

CREAM; VAGINAL

AVC

AT	+	NOVAVAX	15%	N06530 003	JAN 27, 1987	JAN	CAHN
		SUPPOSITORY; VAGINAL					
	+	NOVAVAX	1.05GM	N06530 004	JAN 27, 1987	JAN	CAHN

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HCL

AB	ZENITH GOLDLINE	EQ 1MG BASE	N75614 002	JAN 30, 2001	JAN	NEWA
AB		EQ 2MG BASE	N75614 001	JAN 30, 2001	JAN	NEWA
AB		EQ 5MG BASE	N75614 003	JAN 30, 2001	JAN	NEWA
AB		EQ 10MG BASE	N75614 004	JAN 30, 2001	JAN	NEWA

THYROGLOBULIN

>D>		TABLET; ORAL					
>D>		THYROGLOBULIN					
>D>	+	IMPAK LABS	64.8MG	N80151 001	AUG 07, 1973	FEB	DISC
>A>	@		64.8MG	N80151 001	AUG 07, 1973	FEB	DISC

TRIAMCINOLONE

TABLET; ORAL

TRIAMCINOLONE

>D>	BP	IMPAK LABS	4MG	N84340 001	APR 22, 1975	FEB	DISC
>A>	@		4MG	N84340 001	APR 22, 1975	FEB	DISC

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE

>D>	AT	TOPIDERM	0.025%	N89274 001	FEB 21, 1989	FEB	WDRP
>D>	AT		0.1%	N89275 001	FEB 21, 1989	FEB	WDRP
>D>	AT		0.5%	N89276 001	FEB 21, 1989	FEB	WDRP
>A>	@		0.025%	N89274 001	FEB 21, 1989	FEB	WDRP
>A>	@		0.1%	N89275 001	FEB 21, 1989	FEB	WDRP
>A>	@		0.5%	N89276 001	FEB 21, 1989	FEB	WDRP

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLOREX

>D>	BP	LANNETT	4MG	N85630 001	MAY 16, 1977	FEB	WDRP
>A>	@		4MG	N85630 001	MAY 16, 1977	FEB	WDRP

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

AB	GENEVA PHARMS TECH	EQ 1MG BASE	N40153 001	OCT 25, 1996	JAN CAHN
AB		EQ 2MG BASE	N40153 002	OCT 25, 1996	JAN CAHN
AB		EQ 5MG BASE	N40153 003	OCT 25, 1996	JAN CAHN
AB		EQ 10MG BASE	N40153 004	OCT 25, 1996	JAN CAHN

VITAMIN A PALMITATE

CAPSULE; ORAL

VITAMIN A

>D>	AA	WEST WARD	EQ 50,000 UNITS BASE	N80967 001	MAY 04, 1973	FEB WDRP
>A>		@	EQ 50,000 UNTIS BASE	N80967 001	MAY 04, 1973	FEB WDRP

ZIPRASIDONE HYDROCHLORIDE

>A> CAPSULE; ORAL

>A> GEODON

>A>	PFIZER	20MG	N20825 001	FEB 05, 2001	FEB NEWA
>A>		40MG	N20825 002	FEB 05, 2001	FEB NEWA
>A>		60MG	N20825 003	FEB 05, 2001	FEB NEWA
>A>	+	80MG	N20825 004	FEB 05, 2001	FEB NEWA

ZOLMITRIPTAN

>A> TABLET, ORALLY DISINTEGRATING; ORAL

>A> ZOMIG-ZMT

>A> ASTRazeneca 2.5MG

N21231 001 FEB 13, 2001 FEB NEWA

PREScription DRUG PRODUCT LIST - 21ST EDITION
OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - FEB 2001

2-1

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TAVIST-D

⑧ NOVARTIS

1.34MG;75MG

N18298 002 AUG 21, 1992 JAN DISC

⑧

1.34MG;75MG

N20640 001 AUG 09, 1996 JAN DISC

MICONAZOLE NITRATE

>A> CREAM; TOPICAL, VAGINAL

>A> MONISTAT 3 COMBINATION PACK

>A> + PERSONAL PRODS 2%,4%

N21261 001 FEB 02, 2001 FEB NEWA

**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 '01

NO FEBRUARY 2001 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 Products Designations and Approvals List
February 2001

Name:

Generic Name

TN=Trade Name

Indication Designated:

Sponsor & Address

DD=Date Designated

MA=Marketing Approval

Alendronate disodium TN=Fosamax	Treatment of the bone manifestations of Gaucher disease	Richard J. Wenstrup, M.D. Division of Human Genetics Children's Hospital Research Cincinnati OH 45229-3039 DD= 2/13/01 MA=
B Lymphocyte Stimulator TN=BLyS	Treatment of common variable immunodeficiency (CVID)	Human Genome Sciences, Inc. 9410 Key West Avenue Rockville MD 20850 DD= 2/21/01 MA=
Imatinib TN=Glivec	Treatment of chronic myelogenous leukemia	Novartis Pharmaceuticals 59 Route 10 East Hanover NJ 07936-1080 DD= 1/31/01 MA=
Medroxyprogesterone acetate TN=Hematrol	Treatment of immune thrombocytopenic purpura.	InKine Pharmaceutical Company, 1787 Sentry Parkway West Building 18, Suite 440 Blue Bell PA 19422 DD= 2/22/01 MA=
MTC-DOX for Injection TN=	Treatment of hepatocellular carcinoma	FeRx Incorporated 4330 La Jolla Village Drive Suite #250 San Diego CA 92122 DD= 1/3/01 MA=

Orphan Products Designations and Approvals List
February 2001

Name: Generic Name <u>TN=Trade Name</u>	<u>Indication Designated:</u>	Sponsor & Address DD=Date Designated <u>MA=Marketing Approval</u>
Nitroprusside TN=	Treatment and prevention of cerebral vasospasm following subarachnoid hemorrhage.	Thomas, MD, Jeffrey Evan Thomas Jefferson University and 834 Walnut Street, Suite 650 Philadelphia PA 19107-5102 DD= 2/21/01 MA=
Novel Acting Thrombolytic (NAT) TN=	Treatment of peripheral arterial occlusion (PAO)	Amgen, Inc. One Amgen Center Drive Thousand Oaks CA 91320-1799 DD= 1/26/01 MA=
Polyethylene glycol (PEG)-uricase TN=	To control the clinical consequences of hyperuricemia in patients with severe gout in whom conventional therapy is contraindicated or has been ineffective.	Bio-Technology General Corporation 70 Wood Avenue South Iselin NJ 08830 DD= 2/21/01 MA=
Pyruvate TN=	Treatment of interstitial lung disease.	Cellular Sciences, Inc 84 park Avenue P.O. Box 968 Flemington NJ 08822 DD= 2/21/01 MA=
Recombinant Human Alpha-Fetoprotein TN=	Treatment of myasthenia gravis	Atlantic Biopharmaceuticals, Inc. 50 Church Street 5th floor Cambridge MA 02138 DD= 2/22/01 MA=
Synthetic Human Parathyroid Hormone 1-34 TN=	Treatment of hypoparathyroidism	Orphan Pharmaceuticals, U.S., Inc. 1101 Kermit Drive, Suite 608 Nashville TN 37217 DD= 1/26/01 MA=

Orphan Products Designations and Approvals List
Febuary 2001

Name:

Generic Name

TN=Trade Name

Indication Designated:

Sponsor & Address

DD=Date Designated

MA=Marketing Approval

Virulizin
TN=Virulizin

Treatment of pancreatic cancer.

Lorus Therapeutics Inc.

7100 Woodbine Avenue, Suite 215
Markham, ON L3R 5J2
Canada

DD= 2/1/01

MA=

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

NO FEBRUARY 2001 ADDITIONS

**PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**

PATIENTS AND EXCLUSIVELY FOR DATA

*PED and PED represent Pediatric Exclusivity

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

APPL/PROD NUMBER	INGREDIENT NAME ; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD> 020705 001	DELAVIDRINE MESYLATE;RESCRIPTOR	6177101	JUN 11, 2018			NP	OCT 16, 2003
021005 001	DICLOFENAC SODIUM;SOLARAZE	4861759	AUG 29, 2006	U-248			
020154 002	DIDANOSINE;VIDEX	5254539	AUG 29, 2006	U-248			
>ADD> 020154 003	DIDANOSINE;VIDEX	5880106	JUL 22, 2011				
>ADD> 020154 004	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248			
>ADD> 020154 005	DIDANOSINE;VIDEX	5254539	AUG 29, 2006	U-248			
>ADD> 020154 006	DIDANOSINE;VIDEX	5880106	JUL 22, 2011				
>ADD> 020155 003	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248			
>ADD> 020155 004	DIDANOSINE;VIDEX	5254539	AUG 29, 2006	U-248			
>ADD> 020155 005	DIDANOSINE;VIDEX	5880106	JUL 22, 2011				
>ADD> 020156 001	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248			
>ADD> 021183 001	DIDANOSINE;VIDEX EC	5254539	AUG 29, 2006	U-248			
>ADD> 021183 002	DIDANOSINE;VIDEX EC	4861759	AUG 29, 2006	U-248			
>ADD> 021183 003	DIDANOSINE;VIDEX EC	5254539	AUG 29, 2006	U-248			
>ADD> 021183 004	DIDANOSINE;VIDEX EC	4861759	AUG 29, 2006	U-248			
>ADD> 020623 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011				
>ADD> 020623 002	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011				
>ADD> 020624 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011				
>ADD> 018998 001	ENALAPRIL MALEATE;VASOTEC	4486420	DEC 04, 2001	M-7	DEC 13, 2004		
>ADD> 018998 002	ENALAPRIL MALEATE;VASOTEC	4692435	DEC 24, 2004	M-7	DEC 13, 2004		
>ADD> 018998 003	ENOXAPARIN SODIUM;LOVENOX	5389618	FEB 14, 2012	M-7	DEC 13, 2004		
>ADD> 018998 005	ENOZAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122			
020164 002		4692435	DEC 24, 2004	U-123			
020164 003		5389618	FEB 14, 2012	U-122			
020164 004		4486420	DEC 04, 2001	U-123			
		4692435	DEC 24, 2004				
		5389618	FEB 14, 2012				

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

* PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
020164 004	ENOXAPARIN SODIUM; LOVENOX	4486420	DEC 04, 2001			U-122	
		4692435	DEC 24, 2004			U-123	
		5389618	FEB 14, 2012				
020164 005	ENOXAPARIN SODIUM; LOVENOX	4486420	DEC 04, 2001			U-122	
		4692435	DEC 24, 2004			U-123	
		5389618	FEB 14, 2012				
020164 006	ENOXAPARIN SODIUM; LOVENOX	4486420	DEC 04, 2001			U-122	
		4692435	DEC 24, 2004			U-123	
		5389618	FEB 14, 2012				
020164 007	ENOXAPARIN SODIUM; LOVENOX	4486420	DEC 04, 2001			U-122	
		4692435	DEC 24, 2004			U-123	
		5389618	FEB 14, 2012				
020164 008	ENOXAPARIN SODIUM; LOVENOX	4486420	DEC 04, 2001			U-122	
		4692435	DEC 24, 2004			U-123	
		5389618	FEB 14, 2012				
>ADD>	ESOMEPRAZOLE MAGNESIUM; NEXIUM	6147103	OCT 09, 2018			NP	FEB 20, 2004
>ADD>		6166213	OCT 09, 2018				
>ADD>		6191148	OCT 09, 2018				
>ADD>		4255431	APR 05,	2001		U-373	
>ADD>		4738974	APR 19,	2005		U-373	
>ADD>		4636499	MAY 30,	2005		U-373	
>ADD>		5900424	MAY 04,	2016		U-373	
>ADD>		4786505	APR 20,	2007		U-373	
>ADD>		4853230	APR 20,	2007		U-373	
>ADD>		5714504	FEB 03,	2015		U-373	
>ADD>		5877192	MAY 27,	2014		U-373	
>ADD>		5093342	FEB 02,	2010		U-373	
>ADD>		5599794	FEB 04,	2014		U-373	
>ADD>		5629305	FEB 04,	2014		U-373	
>ADD>		5690960	NOV 25,	2014		U-373	
>ADD>		6147103	OCT 09,	2018		NP	FEB 20, 2004
>ADD>		6166213	OCT 09,	2018			
>ADD>		6191148	OCT 09,	2018			
>ADD>		4255431	APR 05,	2001			
>ADD>		4738974	APR 19,	2005			
>ADD>		4636499	MAY 30,	2005			
>ADD>		5900424	MAY 04,	2016			
>ADD>		4786505	APR 20,	2007			
>ADD>		4853230	APR 20,	2007			
>ADD>		5714504	FEB 03,	2015			
>ADD>		5877192	MAY 27,	2014			
>ADD>		5093342	FEB 02,	2010			
>ADD>		5599794	FEB 04,	2014			
>ADD>		5629305	FEB 04,	2014			
>ADD>		5690960	NOV 25,	2014			
>ADD>		6147103	OCT 09,	2018			
>ADD>		6166213	OCT 09,	2018			
>ADD>		6191148	OCT 09,	2018			
>ADD>		4255431	APR 05,	2001			
>ADD>		4738974	APR 19,	2005			
>ADD>		4636499	MAY 30,	2005			
>ADD>		5900424	MAY 04,	2016			
>ADD>		4786505	APR 20,	2007			
>ADD>		4853230	APR 20,	2007			
>ADD>		5714504	FEB 03,	2015			
>ADD>		5877192	MAY 27,	2014			
>ADD>		5093342	FEB 02,	2010			
>ADD>		5599794	FEB 04,	2014			
>ADD>		5629305	FEB 04,	2014			
>ADD>		5690960	NOV 25,	2014			

*PED and PED represent Pediatric Exclusivity Data

*PED and PED represent Pediatric Exclusivity

הארץ מושבם ישבו ותבונתם תבונת הארץ

INGREDIENT NAME : TRADE NAME

PATENT / PED EXCL USE EXCLUS
EXPIRES CODE CODE EXPIRES

APPL/PROD NUMBER	INGREDIENT NAME ; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	EXCL CODE	EXCLUS EXPRIES	
021121 001	METHYLPHENIDATE HYDROCHLORIDE ; CONCERTA	4 783337	SEP 16, 2003	U-372			
021121 002	METHYLPHENIDATE HYDROCHLORIDE ; CONCERTA	4 783337	SEP 16, 2003	U-372	NP	AUG 01, 2003	
021121 003	METHYLPHENIDATE HYDROCHLORIDE ; CONCERTA	4 783337	SEP 16, 2003	U-372	FEB 05,	2004	
019962 001	METOPROLOL SUCCINATE ; TOPROL-XL	4 927640	MAY 22, 2007	I-194			
019962 002	METOPROLOL SUCCINATE ; TOPROL-XL	5 246714	SEP 21, 2010	I-194	FEB 05,	2004	
019962 003	METOPROLOL SUCCINATE ; TOPROL-XL	4 927640	MAY 22, 2007	I-194	FEB 05,	2004	
019962 004	METOPROLOL SUCCINATE ; TOPROL-XL	5 246714	SEP 21, 2010	I-194	FEB 05,	2004	
		4 957745	SEP 18, 2007	U-107	NS	FEB 05,	2004
		5 001161	MAR 19, 2008	U-107	I-194	FEB 05,	2004
		5 081154	JAN 14, 2009	U-107			
021208 001	MIRTAZAPINE ; REMERON SOLTAB	4 927640	MAY 22, 2007	NCE	JUN 14,	2001	
021208 002	MIRTAZAPINE ; REMERON SOLTAB	5 246714	SEP 21, 2010	NCE	JUN 14,	2001	
021208 003	MIRTAZAPINE ; REMERON SOLTAB	5 178878	JAN 12, 2010	NCE	JUN 14,	2001	
019297 001	MITOXANTRONE HYDROCHLORIDE ; NOVANTRONE	5 178878	JAN 12, 2010	NCE	JUN 14,	2001	
020829 002	MONTELUKAST SODIUM ; SINGULAIR	5 565473	FEB 03, 2012	U-228			
020830 001	MONTELUKAST SODIUM ; SINGULAIR	5 565473	FEB 03, 2012	U-228			
020830 002	MONTELUKAST SODIUM ; SINGULAIR	5 565473	FEB 03, 2012	U-228			
>ADD>	021204 001	NATEGLINIDE ; STARLIX	RE34878	MAR 28,			
>ADD>	021204 002	NATEGLINIDE ; STARLIX	54 63116	OCT 21,	2012		
>ADD>	021204 003	NATEGLINIDE ; STARLIX	54 88150	JAN 30,	2013		
>ADD>	021204 004	NATEGLINIDE ; STARLIX	54 88150	JAN 30,	2013		
>ADD>	075269 001	NIFEDIPINE ; NIFEDIPINE	PC	JUN 05,	2001		
>ADD>	075269 002	NIFEDIPINE ; NIFEDIPINE	PC	JUN 05,	2001		
>ADD>	0211008 001	OCTREOTIDE ACETATE ; SANDOSTATIN LAR	5 753618	JUL 08,	2008		
>ADD>	0211008 002	OCTREOTIDE ACETATE ; SANDOSTATIN LAR	5 753618	JUL 08,	2008		
>ADD>	0211008 003	OCTREOTIDE ACETATE ; SANDOSTATIN LAR	5 753618	JUL 08,	2008		
>ADD>	020592 005	OLANZAPINE ; ZYPREXA	5 229382	APR 23,	2011		
>ADD>	021086 001	OLANZAPINE ; ZYPREXA ZYDIS	5 605897	FEB 25,	2014		
>ADD>	021086 002	OLANZAPINE ; ZYPREXA ZYDIS	6 020487	SEP 23,	2017		
>ADD>	021086 003	OLANZAPINE ; ZYPREXA ZYDIS	6 020487	SEP 23,	2017		
>ADD>	021086 004	OLANZAPINE ; ZYPREXA ZYDIS OMEPRAZOLE ; PRILOSEC	6 020487	SEP 23,	2017		
>ADD>	019810 001		4 255431*PED	OCT 05,	2001		
>ADD>			4 636499*PED	JAN 30,	2006		
>ADD>			4 852230*PED	OCT 20,	2007		
>ADD>			5 093334*PED	AUG 02,	2010		
>ADD>			4 786505*PED	OCT 20,	2007		
>ADD>			5 599794*PED	AUG 04,	2014		
>ADD>			6 147103*PED	APR 09,	2019		
>ADD>			6 166213*PED	APR 09,	2018		
>ADD>			4 508905	APR 02,	2002		
>ADD>			6 191148*PED	APR 09,	2019		
>ADD>			6 150380*PED	MAY 10,	2019		
>ADD>			5 629305*PED	AUG 04,	2014		
>ADD>			6 150380	NOV 10,	2018		
>ADD>			6 147103	OCT 09,	2018		
>ADD>			6 166213	OCT 09,	2018		

**PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
and RECOMMENDATION REGARDING EXCLUSIVITY**

*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	PED CODE	USE CODE	EXCLUS EXPIRES
>ADD>	019810 002	OMEPRAZOLE; PRILOSEC	6191148	OCT 09, 2018	U-108	PED DEC 29, 2001
>ADD>			4255431*	PED OCT 05,	2001	
>ADD>			4636499*	PED JAN 30,	2006	
>ADD>			4853230*	PED OCT 20,	2007	U-108
>ADD>			5093342*	PED AUG 02,	2010	U-166
>ADD>			4786505*	PED OCT 20,	2007	
>ADD>			5599794*	PED AUG 04,	2014	U-108
>ADD>			6147103*	PED APR 09,	2019	U-166
>ADD>			6166213*	PED APR 09,	2018	
>ADD>			4508905	PED APR 02,	2002	
>ADD>			6191148*	PED APR 09,	2019	
>ADD>			6150380*	PED MAY 10,	2019	
>ADD>			5629305*	PED AUG 04,	2014	
>ADD>			6150380	NOV 10,	2018	U-188
>ADD>			6147103	OCT 09,	2018	
>ADD>			6166213	OCT 09,	2018	
>ADD>			6191148	OCT 09,	2018	
>ADD>			4255431*	PED OCT 05,	2001	U-108
>ADD>			4636499*	PED JAN 30,	2006	PED DEC 29, 2001
>ADD>			4853230*	PED OCT 20,	2007	U-108
>ADD>			5093342*	PED AUG 02,	2010	U-166
>ADD>			4786505*	PED OCT 20,	2007	U-108
>ADD>			5599794*	PED AUG 04,	2014	U-166
>ADD>			6147103*	PED APR 09,	2019	
>ADD>			6166213*	PED APR 09,	2018	
>ADD>			4508905	PED APR 02,	2002	
>ADD>			6191148*	PED APR 09,	2019	
>ADD>			6150380*	PED MAY 10,	2019	
>ADD>			5629305*	PED AUG 04,	2014	
>ADD>			6150380	NOV 10,	2018	U-188
>ADD>			6147103	OCT 09,	2018	
>ADD>			6166213	NOV 10,	2018	
>ADD>			6191148	OCT 09,	2018	
>ADD>			5763483	DEC 27,	2016	U-376
>ADD>			5866601	FEB 02,	2016	NDF DEC 14, 2003
>ADD>			5952375	FEB 02,	2016	NCE OCT 27, 2004
>ADD>			6124355	MAY 22,	2015	U-378
>ADD>			6124355	MAY 22,	2015	U-378
>ADD>			6124355	MAY 22,	2015	U-378
>ADD>			6150398	MAY 08,	2011	U-380
>ADD>			4758579	JUL 19,	2005	NDF MAR 22, 2004
>ADD>			4721723	DEC 29,	2006	NCE FEB 02, 2005
>ADD>			4839177	JUN 13,	2006	
>ADD>			5422123	JUN 06,	2012	
>ADD>			5789449	JAN 06,	2009	
>ADD>			5872112	MAY 19,	2015	
>ADD>			5900423	MAY 19,	2015	
>ADD>			6063227	APR 23,	2019	
>ADD>			6080759	MAY 19,	2015	U-286
>ADD>			6124291	MAR 17,	2017	U-286
>ADD>			6133289	MAY 19,	2015	U-286
>ADD>			6172333	JAN 15,	2018	

**PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**

*PED and PED represent Pediatric Exclusivity
EXCLUSIVITY AND EXCLUSIVITAT

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	PATENT/PED EXCL USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD> 019627 002	PROPOFOL; DIPRIVAN	4418068	APR 03,	2002	I-322	FEB 20 , 2004
020815 001	RALOXIFENE HYDROCHLORIDE; EVISTA	6063772	JAN 23,	2016	U-375	
020503 001	RIBAVIRIN; REBETOL	6172046	SEP 21,	2017	U-377	D-65
020632 001	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	6152897	JUN 11,	2018	D-65	FEB 16 , 2004
020632 002	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	6152897	JUN 11,	2018	D-65	FEB 16 , 2004
020632 003	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	6152897	JUN 11,	2018		
>ADD> 020280 001	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	JUN 11,	2018		
>ADD> 020280 002	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	JUN 11,	2018		
>ADD> 020280 003	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	JUN 11,	2018		
>ADD> 020280 005	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	JUN 11,	2018		
>ADD> 020280 008	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	JUN 11,	2018		
>ADD> 020280 009	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	JUN 11,	2018		
>ADD> 021257 001	TRAVOPROST; TRAVATAN	6011062	DEC 22,	2014	U-382 NCE	MAR 16 , 2006
>ADD>		5631287	DEC 22,	2014	U-382	
>ADD>		5849792	DEC 22,	2014	U-383	
>ADD>		5889052	AUG 03,	2013	U-383	
>ADD> 021257 002	TRAVOPROST; TRAVATAN	6011062	DEC 22,	2014	U-382 NCE	MAR 16 , 2006
>ADD>		5631287	DEC 22,	2014	U-382	
>ADD>		5849792	DEC 22,	2014	U-383	
>ADD>		5889052	AUG 03,	2013	U-383	
020468 001	TRIACINOLONE ACETONIDE; NASACORT AQ	6143329	JUL 03,	2016	NE	MAR 29 , 2004
020759 001	TROVAFLOXACIN MESYLATE; TROVAN	6187341	JAN 20,	2019	NCE	FEB 05 , 2006
020759 002	TROVAFLOXACIN MESYLATE; TROVAN	6187341	JAN 20,	2019	NCE	FEB 05 , 2006
>ADD> 021304 001	VALGANCICLOVIR HYDROCHLORIDE; VALCYT ZIPRASIDONE HYDROCHLORIDE; GEODON	4831031	MAR 02,	2007	NE	MAR 29 , 2004
>ADD>		5312925	SEP 01,	2012	NCE	FEB 05 , 2006
020825 002	ZIPRASIDONE HYDROCHLORIDE; GEODON	4831031	MAR 02,	2007	NCE	FEB 05 , 2006
020825 003	ZIPRASIDONE HYDROCHLORIDE; GEODON	5312925	SEP 01,	2012	NCE	FEB 05 , 2006
020825 004	ZIPRASIDONE HYDROCHLORIDE; GEODON	4831031	MAR 02,	2007	NCE	FEB 05 , 2006
>ADD>		5312925	SEP 01,	2012		

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, 21ST EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

ABBREVIATIONS

REFERENCES NEW DOSING SCHEDULE

- D-65** CHANGE DOSING AND ADMINISTRATION TO INDICATE MAINTENANCE OF WEIGHT LOSS OVER AN 18 MONTH PERIOD THUS EXTENDING THE USE OF THIS DRUG FROM ONE TO TWO YEARS

NEW INDICATION

- I-321 JUVENILE RHEUMATOID ARTHRITIS
- I-322 USE OF DIPRIVAN IN PATIENTS 3 MONTHS TO 16 YEARS
- I-323 COLORECTAL CANCER
- I-324 REDUCING NEUROLOGIC DISABILITY AND/OR FREQUENCY OF CLINICAL RELAPSES IN PATIENTS WITH SECONDARY (CHRONIC) PROGRESSIVE, PROGRESSIVE RELAPSING, OR WORSENING RELAPSING-REMITTING MULTIPLE SCLEROSIS

MISCELLANEOUS EXCLUSIVITY CODES

- M-6 ADDITIONAL INFORMATION REGARDING CLINICAL STUDIES DONE WITH GLUOPHAGE/GLYBURIDE COMBINATION ADDED TO CLIN PHARM AND DOSING AND ADMIN
- M-7 CLINICAL PHARMACOLOGY IN PEDIATRIC PATIENTS; DOSAGE AND ADMINISTRATION INFORMATION

PATENT USE CODE

- U-372 METHOD FOR ADMINISTERING A BENEFICIAL DRUG TO THE GI TRACT OF AN ANIMAL, WHICH METHOD COMPRISES ADMITTING AN OSMOTIC DEVICE ORALLY INTO THE ANIMAL...
- U-373 GENERAL USE CLAIM SUBMITTED FOR 12 NEXIUM PATIENTS STATING "PERTINENT TO THE CAPSULE FORMULATION FOR NEXIUM AND ITS INDICATIONS FOR THE TREATMENT OF GERD AND ERADICATION OF H.PYLORI TO REDUCE THE RISK OF DUODENAL ULCER RECURRENCE
- U-374 KIT ADAPTED AND DESIGNED TO PROVIDE BOTH DATA ON THE CURRENT REPRODUCTIVE STATUS OF A PATIENT AND CONTRACEPTION FOR THOSE WHO ARE NOT PREGNANT, BUT RECENTLY ENGAGED IN UNPROTECTED SEX
- U-375 METHOD OF USING RIBAVIRIN FOR TREATING A DISEASE RESPONSIVE TO RIBAVIRIN, E.G. HEPATITIS C
- U-376 TREATMENT OF INFLUENZA

PATENT AND EXCLUSIVITY TERMS

REFERENCES PATENT USE CODE

- U-377** METHOD OF TREATING PT WITH CHRONIC HEPATITIS C HAVING HCV GENOTYPE 1 AND VIRAL LOAD GREATER THAN 2 MILLION COPIES/ML TO ERADICATE DETECTABLE HCV-RNA BY ADMIN COMBINATION OF RIBAVIRIN AND INTERFERON ALFA-2B FOR A LEAST 24 WEEKS
- U-378** METHOD FOR TREATING INCONTINENCE
- U-379** METHOD OF TREATINGONYCHROMYCOSIS
- U-380** COMBINATIONS OF TAXOL (PACLITAXEL) AND CISPLATIN WHICH ARE SUITABLE FOR THE TREATMENT OF OVARIAN AND NON-SMALL CELL LUNG CARCINOMAS
- U-381** TREATMENT OF HYPERPHOSPHATEMIA
- U-382** METHOD OF STABLIZING PROSTAGLANDIN
- U-383** METHOD FOR TREATING GLAUCOMA AND OCULAR HYPERTENSION

*U.S. Government Printing Office: 2001— 472-432/21009

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