

**CUMULATIVE
SUPPLEMENT 2
FEBRUARY 2002**



APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

22nd EDITION

Department of Health and Human Services

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

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Prepared By
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Center for Drug Evaluation and Research
Food and Drug Administration

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

22ND EDITION

Cumulative Supplement 2

February 2002

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APPROVED DRUG PRODUCTS
with
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22ND EDITION

CUMULATIVE SUPPLEMENT 2
FEBRUARY 2002

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, 22nd 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 22nd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 23rd 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

FORMER APPLICANT NAME (<u>FORMER ABBREVIATED NAME</u>)	NEW APPLICANT NAME (<u>NEW ABBREVIATED NAME</u>)
DURAMED PHARMACEUTICALS INC (DURAMED)	DURAMED PHARMACEUTICALS INC SUB OF BARR LABORATORIES INC (DURAMED PHARM BARR)
DERMIK LABORATORIES INC (DERMIK LABS)	DERMIK LABORATORIES DIVISION OF AVENTIS PHARMACEUTICALS INC (DERMIK LABS)
DERMIK LABORATORIES INC SUB RORER (DERMIK LABS)	DERMIK LABORATORIES DIVISION OF AVENTIS PHARMACEUTICALS INC (DERMIK LABS)
McNEIL CONSUMER HEALTHCARE DIVISION (McNEIL CONS)	McNEIL CONSUMER AND SPECIALTY PHARMACEUTICALS DIVISION McNEIL PPC (McNEIL CONS SPECLT)

1.3 AVAILABILITY OF THE EDITION

The 22nd 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 \$105.00 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 22nd annual edition of the 2001 Orange Book Patent and Exclusivity List is at <http://www.fda.gov/cder/orange/22bookpub.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 2001) 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 2001</u>	<u>MAR 2002</u>	<u>JUN 2002</u>	<u>SEP 2002</u>
DRUG PRODUCTS LISTED	10166			
SINGLE SOURCE	2665 (26.2%)			
MULTISOURCE	7391 (72.7%)			
THERAPEUTICALLY EQUIVALENT	7105 (69.9%)			
NOT THERAPEUTICALLY	286 (2.8%)			
EQUIVALENT				
EXCEPTIONS ¹	110 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	10			
NUMBER OF APPLICANTS	574			

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

1.5 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form;Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Approval number, product number, and approval date. The last two columns describe the action. 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 preceded 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.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.
WDAG	Withdrawn. The applicant holder has notified the FDA in writing that the product is no longer being marketed resulting in the product approval being withdrawn by mutual agreement. The product will be listed in the Discontinued Section.
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; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	KV PHARM	500MG/15ML;7.5MG/15ML	N40366 001	JAN 23, 2002	JAN	NEWA
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AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AUGMENTIN '400'

>D>	+	GLAXOSMITHKLINE	400MG/5ML;EQ 57MG BASE/5ML	N50725 002	MAY 31, 1996	FEB	CRLD
>A>			400MG/5ML;EQ 57MG BASE/5ML	N50725 002	MAY 31, 1996	FEB	CRLD

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE;

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

ADDERALL 10

>D>		SHIRE LABS	2.5MG;2.5MG;2.5MG;2.5MG	N11522 007	FEB 13, 1996	FEB	CFTG
>A>	AB		2.5MG;2.5MG;2.5MG;2.5MG	N11522 007	FEB 13, 1996	FEB	CFTG
>A>		ADDERALL 20					
>D>		SHIRE LABS	5MG;5MG;5MG;5MG	N11522 008	FEB 13, 1996	FEB	CTFG
>A>	AB		5MG;5MG;5MG;5MG	N11522 008	FEB 13, 1996	FEB	CTFG
>A>		ADDERALL 30					
>D>	+	SHIRE LABS	7.5MG;7.5MG;7.5MG;7.5MG	N11522 010	MAY 12, 1997	FEB	CFTG
>A>	AB +		7.5MG;7.5MG;7.5MG;7.5MG	N11522 010	MAY 12, 1997	FEB	CFTG
>A>		ADDERALL 5					
>D>		SHIRE LABS	1.25MG;1.25MG;1.25MG;1.25MG	N11522 009	MAY 12, 1997	FEB	CFTG
>A>	AB		1.25MG;1.25MG;1.25MG;1.25MG	N11522 009	MAY 12, 1997	FEB	CFTG
>A>		DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE					
>A>	AB	BARR	1.25MG;1.25MG;1.25MG;1.25MG	N40422 001	FEB 11, 2002	FEB	NEWA
>A>	AB		2.5MG;2.5MG;2.5MG;2.5MG	N40422 002	FEB 11, 2002	FEB	NEWA
>A>	AB		5MG;5MG;5MG;5MG	N40422 003	FEB 11, 2002	FEB	NEWA
>A>	AB		7.5MG;7.5MG;7.5MG;7.5MG	N40422 004	FEB 11, 2002	FEB	NEWA

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION

ABELCET

+	ELAN PHARMS	5MG/ML	N50724 001	NOV 20, 1995	JAN	CAHN
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ATROPINE; PRALIDOXIME CHLORIDE

INJECTABLE; INTRAMUSCULAR

ATNAA

>A>	@	US ARMY	2.1MG/0.7ML;600MG/2ML	N21175 001	JAN 17, 2002	FEB	NEWA
	+	@	2.1MG/0.7ML;600MG/2ML	N21175 001	JAN 17, 2002	JAN	NEWA

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

BACITRACIN ZINC AND POLYMYXIN B SULFATE

>A>	AT	ALTANA	500 UNITS/GM;10,000 UNITS/GM	N65022 001	FEB 27, 2002	FEB	NEWA
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BROMOCRIPTINE MESYLATE

TABLET; ORAL

BROMOCRIPTINE MESYLATE

AB	LEK SVCS	EQ 2.5MG BASE	N74631 001	JAN 13, 1998	JAN	CMFD
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BROMOCRIPTINE MESYLATE

TABLET; ORAL

PARLODEL

AB + NOVARTIS

EQ 2.5MG BASE

N17962 001 JUN 28, 1978 JAN CFTG

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPIVACINE HCL PRESERVATIVE FREE

AP INTL MEDICATED 0.25%

N76012 001 JAN 09, 2002 JAN NEWA

AP 0.5%

N76012 002 JAN 09, 2002 JAN NEWA

AP 0.75%

N76012 003 JAN 09, 2002 JAN NEWA

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPIRONE HCL

>A> AB KV PHARM 5MG

N75572 001 FEB 27, 2002 FEB NEWA

>A> AB 10MG

N75572 002 FEB 27, 2002 FEB NEWA

>A> AB 15MG

N75572 003 FEB 27, 2002 FEB NEWA

>A> AB PAR PHARM 5MG

N75467 001 FEB 28, 2002 FEB NEWA

>A> AB 10MG

N75467 003 FEB 28, 2002 FEB NEWA

>A> AB 15MG

N75467 004 FEB 28, 2002 FEB NEWA

>A> AB TEVA 5MG

N75022 001 FEB 28, 2002 FEB NEWA

>A> AB 10MG

N75022 002 FEB 28, 2002 FEB NEWA

>A> AB 15MG

N75022 003 FEB 28, 2002 FEB NEWA

CALCIPOTRIENE

OINTMENT; TOPICAL

DOVONEX

>A> + BRISTOL MYERS SQUIBB 0.005%

N20273 001 DEC 29, 1993 FEB CAHN

>D> + WESTWOOD SQUIBB 0.005%

N20273 001 DEC 29, 1993 FEB CAHN

SOLUTION; TOPICAL

>A> + BRISTOL MYERS SQUIBB 0.005%

N20611 001 MAR 03, 1997 FEB CAHN

>D> + WESTWOOD SQUIBB 0.005%

N20611 001 MAR 03, 1997 FEB CAHN

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

>A> AB APOTEX 200MG

N75948 001 FEB 27, 2002 FEB NEWA

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CARTEOLOL HCL

>A> AT NOVEX 1%

N76097 001 FEB 06, 2002 FEB NEWA

CEFUROXIME AXETIL

TABLET; ORAL

CEFTIN

>D> GLAXOSMITHKLINE EQ 125MG BASE

N50605 001 DEC 28, 1987 FEB CFTG

>A> AB EQ 125MG BASE

N50605 001 DEC 28, 1987 FEB CFTG

>D> EQ 250MG BASE

N50605 002 DEC 28, 1987 FEB CFTG

>A> AB EQ 250MG BASE

N50605 002 DEC 28, 1987 FEB CFTG

>D> + EQ 500MG BASE

N50605 003 DEC 28, 1987 FEB CFTG

>A> AB + EQ 500MG BASE

N50605 003 DEC 28, 1987 FEB CFTG

CEFUROXIME AXETIL

TABLET; ORAL

>A> CEFUROXIME AXETIL

>A>	AB	RANBAXY	EQ 125MG BASE	N65043 003	FEB 15, 2002	FEB	NEWA
>A>	AB		EQ 250MG BASE	N65043 002	FEB 15, 2002	FEB	NEWA
>A>	AB		EQ 500MG BASE	N65043 001	FEB 15, 2002	FEB	NEWA

CERIVASTATIN SODIUM

TABLET; ORAL

BAYCOL

@ BAYER

0.2MG

N20740 003 JUN 26, 1997 JAN DISC

@

0.3MG

N20740 004 JUN 26, 1997 JAN DISC

@

0.4MG

N20740 005 MAY 24, 1999 JAN DISC

@

0.8MG

N20740 006 JUL 24, 2000 JAN DISC

CHORIOGONADOTROPIN ALFA

INJECTABLE; INJECTION

OVIDREL

>D>	+	SERONO	0.25MG/VIAL
>A>	+	SERONO INC	0.25MG/VIAL

N21149 001 SEP 20, 2000 FEB CAHN

N21149 001 SEP 20, 2000 FEB CAHN

CIMETIDINE

TABLET; ORAL

CIMETIDINE

>D>		@ LEK LJUBLJANA	300MG	N74250 002	JUN 29, 1995	FEB	CMFD
>A>	AB		300MG	N74250 002	JUN 29, 1995	FEB	CMFD
>D>		@	400MG	N74250 003	JUN 29, 1995	FEB	CMFD
>A>	AB		400MG	N74250 003	JUN 29, 1995	FEB	CMFD
>D>		@	800MG	N74250 004	JUN 29, 1995	FEB	CMFD
>A>	AB		800MG	N74250 004	JUN 29, 1995	FEB	CMFD

CLINDAMYCIN PHOSPHATE

LOTION; TOPICAL

CLEOCIN T

AB + PHARMACIA AND UPJOHN EQ 1% BASE

N50600 001 MAY 31, 1989 JAN CFTG

CLINDAMYCIN PHOSPHATE

AB ALTANA EQ 1% BASE

N65067 001 JAN 31, 2002 JAN NEWA

>D> SOLUTION; TOPICAL

>D> AT CLAY PARK EQ 1% BASE

N65049 001 MAY 25, 2000 FEB CDFR

>A> SWAB; TOPICAL

>A> AT EQ 1% BASE

N65049 001 MAY 25, 2000 FEB CDFR

CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; CYANOCOBALAMIN, CO-58

>D> N/A; N/A

>D> DICOPAC KIT

>D> AMERSHAM HLTH N/A;N/A;N/A

N17406 001 JUN 10, 1974 FEB DISC

>A> @ N/A;N/A;N/A

N17406 001 JUN 10, 1974 FEB DISC

CYCLOSPORINE

SOLUTION; ORAL

CYCLOSPORINE

AB ABBOTT 100MG/ML

N65025 001 MAR 03, 2000 JAN CMFD

DEFEROXAMINE MESYLATE

INJECTABLE; INJECTION

DESFERAL

>D>	+	NOVARTIS	2MG/VIAL	N16267 002	MAY 25, 2000	FEB	CPOT
>A>	+		2GM/VIAL	N16267 002	MAY 25, 2000	FEB	CPOT

DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

DEXEDRINE

AB	+	GLAXOSMITHKLINE	5MG	N17078 001	AUG 02, 1976	JAN	CFTG
AB	+		10MG	N17078 002	AUG 02, 1976	JAN	CFTG
AB	+		15MG	N17078 003	AUG 02, 1976	JAN	CFTG

DEXTROAMPHETAMINE SULFATE

AB		BARR	5MG	N76137 001	JAN 18, 2002	JAN	NEWA
AB			10MG	N76137 002	JAN 18, 2002	JAN	NEWA
AB			15MG	N76137 003	JAN 18, 2002	JAN	NEWA

TABLET; ORAL

AA		MALLINCKRODT	5MG	N40436 001	JAN 29, 2002	JAN	NEWA
AA			10MG	N40436 002	JAN 29, 2002	JAN	NEWA

DICLOFENAC POTASSIUM

TABLET; ORAL

DICLOFENAC POTASSIUM

>A>	AB	MUTUAL PHARM	50MG	N75470 001	FEB 21, 2002	FEB	NEWA
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DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

DICLOFENAC SODIUM

>A>	AB	ALPHAPHARM	50MG	N75281 002	FEB 12, 2002	FEB	NEWA
>A>	AB		75MG	N75281 003	FEB 12, 2002	FEB	NEWA

TABLET, EXTENDED RELEASE; ORAL

AB		PUREPAC PHARM	100MG	N75910 001	JAN 07, 2002	JAN	NEWA
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EFAVIRENZ

TABLET; ORAL

SUSTIVA

>A>		BRISTOL MYERS SQUIBB	300MG	N21360 001	FEB 01, 2002	FEB	NEWA
>A>	+		600MG	N21360 002	FEB 01, 2002	FEB	NEWA

EPTIFIBATIDE

INJECTABLE; INJECTION

INTEGRILIN

>D>	+	COR	2MG/ML	N20718 001	MAY 18, 1998	FEB	CAHN
>D>	+		75MG/100ML	N20718 002	MAY 18, 1998	FEB	CAHN
>A>	+	MILLENNIUM PHARMS	2MG/ML	N20718 001	MAY 18, 1998	FEB	CAHN
>A>	+		75MG/100ML	N20718 002	MAY 18, 1998	FEB	CAHN

FLUNISOLIDE

SPRAY, METERED; NASAL

FLUNISOLIDE

>A>							
>A>	AB	BAUSCH AND LOMB	0.025MG/SPRAY	N74805 001	FEB 20, 2002	FEB	NEWA
>A>		NASALIDE					

FLUNISOLIDE

SPRAY, METERED; NASAL

NASALIDE

>D>	BX +	IVAX RES	0.025MG/SPRAY	N18148 001	SEP 24, 1981	FEB	CTEC
>A>	AB +		0.025MG/SPRAY	N18148 001	SEP 24, 1981	FEB	CTEC

FLUOCINOLONE ACETONIDE; HYDROQUINONE; TRETINOIN

CREAM; TOPICAL

TRI-LUMA

	+	HILL DERMAC	0.01%;4%;0.05%	N21112 001	JAN 18, 2002	JAN	NEWA
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FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

FLUOXETINE

AB	ALPHAPHARM	EQ 10MG BASE	N75577 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75577 002	JAN 29, 2002	JAN	NEWA
AB	BARR	EQ 10MG BASE	N74803 002	JAN 30, 2002	JAN	NEWA
AB	CARLSBAD	EQ 10MG BASE	N76022 001	JAN 30, 2002	JAN	NEWA
AB		EQ 20MG BASE	N76022 002	JAN 30, 2002	JAN	NEWA
AB	DR REDDYS LABS INC	EQ 10MG BASE	N75465 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75465 002	JAN 29, 2002	JAN	NEWA
AB	EON	EQ 10MG BASE	N75807 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75807 002	JAN 29, 2002	JAN	NEWA
AB	IVAX PHARMS	EQ 10MG BASE	N75245 002	JAN 31, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75245 001	JAN 31, 2002	JAN	NEWA
AB	MALLINCKRODT	EQ 10MG BASE	N75658 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75658 002	JAN 29, 2002	JAN	NEWA
AB	MUTUAL PHARMA	EQ 10MG BASE	N75787 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75787 002	JAN 29, 2002	JAN	NEWA
AB	MYLAN	EQ 10MG BASE	N75207 001	JAN 30, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75207 002	JAN 30, 2002	JAN	NEWA
>A>	AB	EQ 10MG BASE	N76165 001	FEB 01, 2002	FEB	NEWA
>A>	AB	EQ 20MG BASE	N76165 002	FEB 01, 2002	FEB	NEWA
	AB	EQ 10MG BASE	N76001 001	JAN 29, 2002	JAN	NEWA
	AB	EQ 20MG BASE	N76001 002	JAN 29, 2002	JAN	NEWA
	AB	EQ 10MG BASE	N75464 001	JAN 30, 2002	JAN	NEWA
	AB	EQ 20MG BASE	N75464 002	JAN 30, 2002	JAN	NEWA
	AB	EQ 10MG BASE	N75452 001	JAN 29, 2002	JAN	NEWA
	AB	EQ 20MG BASE	N75452 002	JAN 29, 2002	JAN	NEWA
	AB	EQ 40MG BASE	N75452 003	JAN 29, 2002	JAN	NEWA
	AB	EQ 10MG BASE	N75662 001	JAN 29, 2002	JAN	NEWA
	AB	EQ 20MG BASE	N75662 002	JAN 29, 2002	JAN	NEWA
	FLUOXETINE HCL					
	AB	EQ 20MG BASE	N75049 002	JAN 29, 2002	JAN	NEWA
	AB	EQ 40MG BASE	N75049 003	JAN 29, 2002	JAN	NEWA
	SOLUTION; ORAL					
	FLUOXETINE					
	AA	EQ 20MG BASE/5ML	N75690 001	JAN 31, 2002	JAN	NEWA
	AA	EQ 20MG BASE/5ML	N75920 001	JAN 29, 2002	JAN	NEWA
>A>	AA	EQ 20MG BASE/5ML	N75292 001	FEB 07, 2002	FEB	NEWA
	AA	EQ 20MG BASE/5ML	N76015 001	JAN 30, 2002	JAN	NEWA
	TABLET; ORAL					
	FLUOXETINE HCL					

FLUOXETINE HYDROCHLORIDE

TABLET; ORAL

FLUOXETINE HCL

>A>	AB	BARR	EQ 10MG BASE	N75810 001	FEB 01, 2002	FEB	NEWA
	AB	DR REDDYS LABS INC	EQ 10MG BASE	N76006 001	JAN 30, 2002	JAN	NEWA
	AB	EON	EQ 10MG BASE	N76024 001	JAN 29, 2002	JAN	NEWA
	AB	TEVA	EQ 10MG BASE	N75872 001	JAN 29, 2002	JAN	NEWA
>A>	AB	ZENITH GOLDLINE	EQ 10MG BASE	N75865 001	FEB 28, 2002	FEB	NEWA

FOLIC ACID

TABLET; ORAL

FOLIC ACID

>D>	AA	+	DANBURY PHARMA	1MG	N80680 001	DEC 23, 1971	FEB	CAHN
>A>	AA	+	WATSON LABS	1MG	N80680 001	DEC 23, 1971	FEB	CAHN

GLIPIZIDE

TABLET, EXTENDED RELEASE; ORAL

GLUCOTROL XL

>D>		+	PFIZER	2.5MG	N20329 003	AUG 10, 1999	FEB	CRLD
>A>				2.5MG	N20329 003	AUG 10, 1999	FEB	CRLD
>D>		+		5MG	N20329 001	APR 26, 1994	FEB	CRLD
>A>				5MG	N20329 001	APR 26, 1994	FEB	CRLD

IFOSFAMIDE; MESNA

INJECTABLE; INTRAVENOUS

IFOSFAMIDE/MESNA KIT

>A>		+	GENSIA SICOR PHARMS	1GM /20ML(50MG/ML);1GM				
				/10ML(100MG/ML)	N75874 001	FEB 26, 2002	FEB	NEWA
>A>		+		3GM /60ML(50MG/ML);1GM				
				/10ML(100MG/ML)	N75874 002	FEB 26, 2002	FEB	NEWA

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

>A>	AB	ABLE	75MG	N76114 001	FEB 06, 2002	FEB	NEWA
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KETOCONAZOLE

TABLET; ORAL

KETOCONAZOLE

	AB	TORPHARM	200MG	N75912 001	JAN 10, 2002	JAN	NEWA
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KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL

KETOPROFEN

>A>	AB	MYLAN	100MG	N75679 003	FEB 20, 2002	FEB	NEWA
>A>	AB		150MG	N75679 002	FEB 20, 2002	FEB	NEWA
>A>	AB		200MG	N75679 001	FEB 20, 2002	FEB	NEWA

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

KETOROLAC TROMETHAMINE

AP		AM PHARM PARTNERS	15MG/ML	N75784 001	JAN 11, 2002	JAN	NEWA
AP			30MG/ML	N75784 002	JAN 11, 2002	JAN	NEWA

LACTULOSE

SOLUTION; ORAL

LACTULOSE

>A>	AA	NOVEX	10GM/15ML	N75911 001	FEB 21, 2002	FEB	NEWA
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LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS

ELIGARD

+ ATRIX 7.5MG/VIAL

N21343 001 JAN 23, 2002 JAN NEWA

MEFLOQUINE HYDROCHLORIDE

TABLET; ORAL

>A> LARIAM

>D> + ROCHE 250MG

N19591 001 MAY 02, 1989 FEB CFTG

>A> AB + 250MG

N19591 001 MAY 02, 1989 FEB CFTG

>A> MEFLOQUINE HCL

>A> AB GENEVA PHARMS TECH 250MG

N76175 001 FEB 20, 2002 FEB NEWA

MEGESTROL ACETATE

SUSPENSION; ORAL

MEGESTROL ACETATE

>A> AB ROXANE 40MG/ML

N75997 001 FEB 15, 2002 FEB NEWA

MESTRANOL; NORETHINDRONE

TABLET; ORAL-28

NORINYL 1+50 28-DAY

AB WATSON LABS 0.05MG;1MG

N16659 001 NOV 17, 1967 JAN CAHN

METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLUCOPHAGE

AB BRISTOL MYERS SQUIBB 500MG

N20357 001 MAR 03, 1995 JAN CFTG

AB 850MG

N20357 002 MAR 03, 1995 JAN CFTG

AB + 1GM

N20357 005 NOV 05, 1998 JAN CFTG

METFORMIN HCL

AB ALPHAPHARM 500MG

N75969 001 JAN 29, 2002 JAN NEWA

AB 850MG

N75969 002 JAN 29, 2002 JAN NEWA

AB 1GM

N75969 003 JAN 29, 2002 JAN NEWA

AB ANDRX PHARMS 500MG

N75961 001 JAN 25, 2002 JAN NEWA

AB 850MG

N75961 002 JAN 25, 2002 JAN NEWA

AB 1GM

N75961 003 JAN 25, 2002 JAN NEWA

AB BARR 500MG

N75971 001 JAN 25, 2002 JAN NEWA

AB 850MG

N75971 002 JAN 25, 2002 JAN NEWA

AB 1GM

N75971 003 JAN 25, 2002 JAN NEWA

AB CARACO 500MG

N75967 001 JAN 29, 2002 JAN NEWA

AB 850MG

N75967 002 JAN 29, 2002 JAN NEWA

AB 1GM

N75967 003 JAN 29, 2002 JAN NEWA

AB EON 500MG

N75965 001 JAN 25, 2002 JAN NEWA

AB 850MG

N75965 002 JAN 25, 2002 JAN NEWA

AB 1GM

N75965 003 JAN 25, 2002 JAN NEWA

AB GENEVA PHARMS TECH 500MG

N75985 001 JAN 25, 2002 JAN NEWA

AB 850MG

N75985 002 JAN 25, 2002 JAN NEWA

	AB		1GM	N75985 003	JAN 25, 2002	JAN	NEWA
	AB	GENPHARM	500MG	N75973 001	JAN 25, 2002	JAN	NEWA
	AB		850MG	N75973 002	JAN 25, 2002	JAN	NEWA
	AB		1GM	N75973 003	JAN 25, 2002	JAN	NEWA
	AB	GOLDLINE	500MG	N75972 001	JAN 24, 2002	JAN	NEWA
	AB		625MG	N75972 005	JAN 24, 2002	JAN	NEWA
	AB		750MG	N75972 004	JAN 24, 2002	JAN	NEWA
	AB		850MG	N75972 002	JAN 24, 2002	JAN	NEWA
	AB		1GM	N75972 003	JAN 24, 2002	JAN	NEWA
>A>	AB	MUTUAL PHARMA	500MG	N76038 001	FEB 21, 2002	FEB	NEWA
>A>	AB		850MG	N76038 002	FEB 21, 2002	FEB	NEWA
>A>	AB		1GM	N76038 003	FEB 21, 2002	FEB	NEWA
	AB	MYLAN	500MG	N75976 001	JAN 24, 2002	JAN	NEWA
	AB		850MG	N75976 002	JAN 24, 2002	JAN	NEWA
	AB		1GM	N75976 003	JAN 24, 2002	JAN	NEWA
	AB	PUREPAC PHARM	500MG	N76033 001	JAN 24, 2002	JAN	NEWA
	AB		850MG	N76033 002	JAN 24, 2002	JAN	NEWA
	AB		1GM	N76033 003	JAN 24, 2001	JAN	NEWA
	AB	TEVA	500MG	N75978 001	JAN 25, 2002	JAN	NEWA
	AB		850MG	N75978 002	JAN 25, 2002	JAN	NEWA
	AB	WATSON LABS	500MG	N75979 001	JAN 24, 2002	JAN	NEWA
	AB		850MG	N75979 002	JAN 24, 2002	JAN	NEWA
	AB		1GM	N75979 003	JAN 24, 2002	JAN	NEWA
	AB	ZENITH GOLDLINE	500MG	N75975 001	JAN 24, 2002	JAN	NEWA
	AB		625MG	N75975 004	JAN 24, 2002	JAN	NEWA
	AB		750MG	N75975 005	JAN 24, 2002	JAN	NEWA
	AB		850MG	N75975 002	JAN 24, 2002	JAN	NEWA
	AB		1GM	N75975 003	JAN 24, 2002	JAN	NEWA

METHOHEXITAL SODIUM

INJECTABLE; INJECTION

BREVITAL SODIUM

>A>	+	KING PHARMS	500MG/VIAL	N11559 001	JUN 27, 1960	FEB	CAHN
>A>	+		2.5GM/VIAL	N11559 002	JUN 27, 1960	FEB	CAHN
>A>	+		5GM/VIAL	N11559 003	MAY 08, 1961	FEB	CAHN
>D>	+	LILLY	500MG/VIAL	N11559 001	JUN 27, 1960	FEB	CAHN
>D>	+		2.5GM/VIAL	N11559 002	JUN 27, 1960	FEB	CAHN
>D>	+		5GM/VIAL	N11559 003	MAY 08, 1961	FEB	CAHN

METHYLPHENIDATE HYDROCHLORIDE

TABLET; ORAL

METHYLPHENIDATE HCL

>A>	AB	PUREPAC PHARM	5MG	N40321 001	FEB 05, 2002	FEB	NEWA
>A>	AB		10MG	N40321 002	FEB 05, 2002	FEB	NEWA
>A>	AB		20MG	N40321 003	FEB 05, 2002	FEB	NEWA

NABUMETONE

TABLET; ORAL

NABUMETONE

>A>	AB	EON	500MG	N75280 001	FEB 25, 2002	FEB	NEWA
>A>	AB		750MG	N75280 002	FEB 25, 2002	FEB	NEWA
>A>	AB	INVAMED	500MG	N75590 001	FEB 25, 2002	FEB	NEWA
>A>	AB		750MG	N75590 002	FEB 25, 2002	FEB	NEWA

NISOLDIPINETABLET, EXTENDED RELEASE; ORAL
SULAR

>D>	+	ASTRAZENECA	10MG	N20356 001	FEB 02, 1995	FEB	CAHN
>D>	+		20MG	N20356 002	FEB 02, 1995	FEB	CAHN
>D>	+		40MG	N20356 004	FEB 02, 1995	FEB	CAHN
>A>	+	WHITEHALL ROBINS	10MG	N20356 001	FEB 02, 1995	FEB	CAHN
>A>			20MG	N20356 002	FEB 02, 1995	FEB	CAHN
>A>	+		40MG	N20356 004	FEB 02, 1995	FEB	CAHN

NITISINONE

CAPSULE; ORAL

ORFADIN

R R REGISTRATIONS

		2MG	N21232 001	JAN 18, 2002	JAN	NEWA
		5MG	N21232 002	JAN 18, 2002	JAN	NEWA
+		10MG	N21232 003	JAN 18, 2002	JAN	NEWA

NITROFURANTOIN

SUSPENSION; ORAL

FURADANTIN

+	FIRST HORIZON	25MG/5ML	N09175 001	DEC 23, 1953	JAN	CAHN
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OFLOXACIN

INJECTABLE; INJECTION

FLOXIN

AP	+	JOHNSON RW	40MG/ML	N20087 003	MAR 31, 1992	JAN	CFTG
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AP		BEDFORD	40MG/ML	N75762 001	JAN 16, 2002	JAN	NEWA
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OXAPROZIN

TABLET; ORAL

OXAPROZIN

AB		CARACO	600MG	N75844 001	JAN 03, 2002	JAN	NEWA
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PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

AA		VINTAGE PHARMS	37.5MG	N40377 001	JAN 04, 2002	JAN	NEWA
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PODOFILOX

SOLUTION; TOPICAL

CONDYLOX

AT	+	PADDOCK	0.5%	N19795 001	DEC 13, 1990	JAN	CFTG
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AT		PADDOCK	0.5%	N75600 001	JAN 29, 2002	JAN	NEWA
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PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL

PHENERGAN

>D>	BR	+	WYETH AYERST	25MG	N10926 001	MAY 05, 1958	FEB	CTEC
>A>	AB	+		25MG	N10926 001	MAY 05, 1958	FEB	CTEC
>A>			PROMETHAZINE HCL					

PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL

>A>	PROMETHAZINE HCL				
>A>	AB	G AND W LABS	25MG	N40428 001	FEB 05, 2002 FEB NEWA

PROPAFENONE HYDROCHLORIDE

TABLET; ORAL

PROPAFENONE HCL

>A>	AB	KV PHARM	150MG	N76193 001	FEB 07, 2002 FEB NEWA
>A>	AB		225MG	N76193 002	FEB 07, 2002 FEB NEWA
>A>	AB		300MG	N76193 003	FEB 07, 2002 FEB NEWA

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

>D>	AB	LEDERLE	60MG	N71495 001	DEC 31, 1987 FEB DISC
>A>		@	60MG	N71495 001	DEC 31, 1987 FEB DISC
>D>	AB		90MG	N71496 001	DEC 31, 1987 FEB DISC
>A>		@	90MG	N71496 001	DEC 31, 1987 FEB DISC

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

AB	VINTAGE PHARMS	500MG	N40349 001	JAN 11, 2002 JAN NEWA
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TABLET, DELAYED RELEASE; ORAL

AZULFIDINE EN-TABS

AB +	PHARMACIA AND UPJOHN	500MG	N07073 002	APR 06, 1983 JAN CFTG
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SULFASALAZINE

AB	VINTAGE PHARMS	500MG	N75339 001	JAN 11, 2002 JAN NEWA
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TERBUTALINE SULFATE

INJECTABLE; INJECTION

BRETHINE

>A>	+	NEOSAN PHARMS	1MG/ML	N18571 001	NOV 30, 1981 FEB CAHN
>D>	+	NOVARTIS	1MG/ML	N18571 001	NOV 30, 1981 FEB CAHN

TABLET; ORAL

>A>	AB	NEOSAN PHARMS	2.5MG	N17849 001	MAY 17, 1976 FEB CAHN
>A>	AB +		5MG	N17849 002	MAY 17, 1976 FEB CAHN
>D>	AB	NOVARTIS	2.5MG	N17849 001	MAY 17, 1976 FEB CAHN
>D>	AB +		5MG	N17849 002	MAY 17, 1976 FEB CAHN

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL

TESTODERM TTS

BX +	ALZA	5MG/24HR	N20791 001	DEC 18, 1997 JAN CTNA
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TETRACYCLINE HYDROCHLORIDE

FIBER, EXTENDED RELEASE; PERIODONTAL

ACTISITE

>A>	+	ALZA	12.7MG/FIBER	N50653 001	MAR 25, 1994 FEB CAHN
>D>	+	ON SITE ALZA	12.7MG/FIBER	N50653 001	MAR 25, 1994 FEB CAHN

THIOTEPA

INJECTABLE; INJECTION

THIOTEPA

>D>	AP	AAIPHARMA	15MG/VIAL	N75698 001	SEP 20, 2001	FEB	CAHN
>A>	AP	AM PHARM PARTNERS	15MG/VIAL	N75698 001	SEP 20, 2001	FEB	CAHN

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL INTENSOL

@ ROXANE

EQ 5MG BASE/ML

N73494 001 JUN 30, 1992 JAN DISC

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

TOBRAMYCIN

>A>	AT	NOVEX	0.3%	N65087 001	FEB 25, 2002	FEB	NEWA
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TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

>D>	AP	ASTRAZENECA	EQ 40MG BASE/ML	N63120 001	OCT 31, 1994	FEB	DISC
>A>		@	EQ 40MG BASE/ML	N63120 001	OCT 31, 1994	FEB	DISC
		@	EQ 40MG BASE/ML	N63122 001	OCT 31, 1994	JAN	DISC

TOPIRAMATE

TABLET; ORAL

TOPAMAX

+ JOHNSON AND JOHNSON

25MG

N20505 004 DEC 24, 1996 JAN CAHN

@

50MG

N20505 005 DEC 24, 1996 JAN CAHN

100MG

N20505 001 DEC 24, 1996 JAN CAHN

200MG

N20505 002 DEC 24, 1996 JAN CAHN

@

300MG

N20505 003 DEC 24, 1996 JAN CAHN

@

400MG

N20505 006 DEC 24, 1996 JAN CAHN

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

ULTRAM

>A> + JOHNSON AND JOHNSON

50MG

N20281 002 MAR 03, 1995 FEB CAHN

>A> @

100MG

N20281 001 MAR 03, 1995 FEB CAHN

>D> + JOHNSON RW

50MG

N20281 002 MAR 03, 1995 FEB CAHN

>D> @

100MG

N20281 001 MAR 03, 1995 FEB CAHN

TRIMETHOBENZAMIDE HYDROCHLORIDE

CAPSULE; ORAL

TIGAN

+ KING PHARMS

300MG

N17531 006 DEC 13, 2001 JAN NEWA

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HCL

>D> AP STERIS

100MG/ML

N87939 001 DEC 28, 1982 FEB DISC

>A> @

100MG/ML

N87939 001 DEC 28, 1982 FEB DISC

URSODIOL

CAPSULE; ORAL

ACTIGALL

>D>		@ NOVARTIS	150MG	N19594 001	DEC 31, 1987	FEB	CAHN
>D>	AB	+	300MG	N19594 002	DEC 31, 1987	FEB	CAHN
>A>		@ WATSON PHARMS	150MG	N19594 001	DEC 31, 1987	FEB	CAHN
>A>	AB	+	300MG	N19594 002	DEC 31, 1987	FEB	CAHN

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

>D>	CAPSULE, EXTENDED RELEASE; ORAL				
	CONTAC 12 HOUR				
	@ GLAXOSMITHKLINE	8MG;75MG	N18099 001	FEB 04, 1980	JAN DISC
>D>	PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE				
>D>	+ CENT PHARMS	8MG;75MG	N18809 001	MAY 07, 1984	FEB DISC
>A>	@	8MG;75MG	N18809 001	MAY 07, 1984	FEB DISC

INSULIN PURIFIED PORK

	INJECTABLE; INJECTION				
>D>	REGULAR PURIFIED PORK INSULIN				
>D>	+ NOVO NORDISK	100 UNITS/ML	N18381 001	MAR 17, 1980	FEB DISC
>A>	@	100 UNITS/ML	N18381 001	MAR 17, 1980	FEB DISC

INSULIN SUSP ISOPHANE PURIFIED PORK

	INJECTABLE; INJECTION				
>D>	NPH PURIFIED PORK ISOPHANE INSULIN				
>D>	+ NOVO NORDISK	100 UNITS/ML	N18623 001	JUL 30, 1981	FEB DISC
>A>	@	100 UNITS/ML	N18623 001	JUL 30, 1981	FEB DISC

INSULIN ZINC SUSP PURIFIED PORK

	INJECTABLE; INJECTION				
>D>	LENTE				
>D>	NOVO NORDISK	100 UNITS/ML	N18383 001	MAR 17, 1980	FEB DISC
>A>	@	100 UNITS/ML	N18383 001	MAR 17, 1980	FEB DISC

KETOPROFEN

	TABLET; ORAL				
	KETOPROFEN				
>A>	PERRIGO	12.5MG	N75364 001	FEB 07, 2002	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 '02

NO FEBRUARY 2002 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 2002

Generic **Bioartificial liver system utilizing xenogenic hepatocytes** Trade NONE ASSIGNED
Name: **in a hollow fiber bioreactor cartridge (BAL)** Name:
Designated *Treatment of patients with acute liver failure presenting with encephalopathy deteriorating beyond*
Parson's grade
Indication: 2
Sponsor: Excorp Medical, Inc. Date Designated: 2/11/2002
Address: Suite 235 Market Approval Date: Not currently Approved
7200 Hudson Blvd.
Oakdale MN 55128

Generic **carbamic acid,** Trade NONE ASSIGNED
Name: **[[4-[[3-[[4-[1-(4-hydroxyphenyl)-1-methyl-ethyl]phenoxy]m** Name:
ethyl]phenyl]methoxy]-phenyl]iminomethyl]-,ethyl ester
Designated *Management of cystic fibrosis*
Indication:
Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc Date Designated: 1/15/2002
Address: 900 Ridgebury Road Market Approval Date: Not currently Approved
P.O. Box 368
Ridgefield CT 06877

Generic **clofarabine** Trade Clofarex
Name: Name:
Designated *Treatment of acute lymphoblastic leukemia*
Indication:
Sponsor: Ilex Products, Inc. Date Designated: 2/7/2002
Address: 4545 Horizon Hill Blvd. Market Approval Date: Not currently Approved
San Antonio TX 78229-2263

Generic **creatine** Trade Creapure
Name: Name:
Designated *Treatment of amyotrophic lateral sclerosis*
Indication:
Sponsor: Avicena Group, Inc. Date Designated: 2/12/2002
Address: 580 California St. Market Approval Date: Not currently Approved
Suite 1600
San Francisco CA 94104

Orphan Products Designations and Approvals List

February 2002

Generic Name:	homoharringtonine	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment for chronic myelogenous leukemia</i>		
Sponsor:	American BioScience, Inc.	Date Designated:	2/8/2002
Address:	2730 Wilshire Blvd. #110 Santa Monica CA 90403	Market Approval Date:	Not currently Approved
Generic Name:	human anti-transforming growth factor beta 1 monoclonal antibody	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment of systemic sclerosis</i>		
Sponsor:	Genzyme Corporation	Date Designated:	1/11/2002
Address:	One Kendall Square Cambridge MA 02139	Market Approval Date:	Not currently Approved
Generic Name:	I(131)-TM-601 (chlorotoxin)	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>treatment of malignant glioma</i>		
Sponsor:	TransMolecular, Inc.	Date Designated:	2/14/2002
Address:	3800 Colonnade Parkway Suite 240 Birmingham AL 35243	Market Approval Date:	Not currently Approved
Generic Name:	lactic acid bacteria (Lactobacilli, Bifidobacteria, and Streptococci)	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment of active chronic pouchitis</i>		
Sponsor:	VSL Pharmaceuticals, Inc.	Date Designated:	1/15/2002
Address:	800 S. Frederick Avenue Gaithersburg MD 20877	Market Approval Date:	Not currently Approved
Generic Name:	lactic acid bacteria (Lactobacilli, Bifidobacteria, and Streptococcus species)	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Prevention of disease relapse in patients with chronic pouchitis</i>		
Sponsor:	VSL Pharmaceuticals, Inc.	Date Designated:	1/15/2002
Address:	800 S. Frederick Ave. Gaithersburg MD 20877	Market Approval Date:	Not currently Approved

Orphan Products Designations and Approvals List

February 2002

Generic Name:	lipase, amylase, and protease	Trade Name:	TheraCLEC-Total
Designated Indication:	<i>Treatment of pancreatic insufficiency</i>		
Sponsor:	Altus Biologics Inc.	Date Designated:	1/23/2002
Address:	625 Putnam Avenue Cambridge MA 02139	Market Approval Date:	Not currently Approved

Generic Name:	nitazoxanide	Trade Name:	Cryptaz
Designated Indication:	<i>Treatment of intestinal giardiasis</i>		
Sponsor:	Romark Laboratories, L.C.	Date Designated:	2/14/2002
Address:	6200 Courtney Campbell Causeway Suite 880 Tampa FL 33607	Market Approval Date:	Not currently Approved

Generic Name:	phenylephrine	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment of ileal pouch anal anastomosis related fecal incontinence</i>		
Sponsor:	S.L.A. Pharma	Date Designated:	2/14/2002
Address:	Unit 3, Hill Farm Industrial Estate Leavesden, Watford United Kingdom WD25 7SA	Market Approval Date:	Not currently Approved

Generic Name:	recombinant human endostatin protein	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment of metastatic melanoma</i>		
Sponsor:	EntreMed, Inc.	Date Designated:	2/21/2002
Address:	9640 Medical Center Drive Rockville MD 20850	Market Approval Date:	Not currently Approved

Generic Name:	SSI(dsFv)-PE38	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment of epithelial ovarian cancer</i>		
Sponsor:	NeoPharm, Inc.	Date Designated:	2/11/2002
Address:	150 Field Drive Suite 195 Lake Forest IL 60045	Market Approval Date:	Not currently Approved

Orphan Products Designations and Approvals List
February 2002

Generic **SS1(dsFv)-PE38**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of malignant mesothelioma*
Indication:

Sponsor: NeoPharm Incorporated
Address: 150 Field Drive
Suite 195
Lake Forest IL 60045

Date Designated: 2/11/2002
Market Approval Date: Not currently Approved

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

NO FEBRUARY 2002 ADDITIONS

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
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020503 001	ALBUTEROL SULFATE; PROVENTIL-HFA	6352684	NOV 28, 2009			
021303 001	AMPHETAMINE ASPARTATE; ADDERALL XR 10	6322819	NOV 27, 2018			
021303 002	AMPHETAMINE ASPARTATE; ADDERALL XR 20	6322819	NOV 27, 2018			
021303 003	AMPHETAMINE ASPARTATE; ADDERALL XR 30	6322819	NOV 27, 2018			
020883 001	ARGATROBAN; ARGATROBAN					
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020911 002	BECLOMETHASONE DIPROPIONATE; QVAR 40	6352684	NOV 28, 2009			
020911 001	BECLOMETHASONE DIPROPIONATE; QVAR 80	6352684	NOV 28, 2009			
018731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR					
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018731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR					
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018731 004	BUSPIRONE HYDROCHLORIDE; BUSPAR					
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020954 001	BUSULFAN; BUSULFEX	5430057	SEP 30, 2013	U-263	ODE	FEB 04, 2006
		5559148	MAY 24, 2015	U-264	NDF	FEB 04, 2002
		5430057*PED	MAR 30, 2014	U-263	PED	AUG 04, 2002
		5559148*PED	NOV 24, 2015	U-264	PED	AUG 04, 2006
019835 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2007			
		4525358*PED	DEC 25, 2007			
019835 002	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2007			
		4525358*PED	DEC 25, 2007			
020346 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2007			
		4525358*PED	DEC 25, 2007			
020839 001	CLOPIDOGREL BISULFATE; PLAVIX					
021165 001	DESLOMATADINE; CLARINEX	6100274	JUL 07, 2019			
075863 001	DESGESTREL; DESGESTREL AND ETHI					
020655 001	ESTRADIOL; ALORA					
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020655 003	ESTRADIOL; ALORA					
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075753 002	FENOFIBRATE; FENOFIBRATE					
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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

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075753 003	FONDAPARINUX SODIUM; ARIXTRA	5084479	JAN 02, 2010	U-258		
021345 001	GABAPENTIN; NEURONTIN	5084479*	JUL 02, 2010	U-258		
020235 001		5084479	JAN 02, 2010	U-258		
020235 002	GABAPENTIN; NEURONTIN	5084479*	JUL 02, 2010	U-258		
020235 003	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-258		
020622 001	GLATIRAMER ACETATE; COPAXONE	5084479*	JUL 02, 2010	U-258		
020387 001	HYDROCHLOROTHIAZIDE; HYZAAR	6342476	MAY 24, 2014	U-441		
		5153197	OCT 06, 2009	U-3		
		5138069	AUG 11, 2009			
		5608075	MAR 04, 2014			
		5138069*	FEB 11, 2010			
		5153197*	APR 06, 2010	U-3		
		5608075*	SEP 04, 2014			
020387 002	HYDROCHLOROTHIAZIDE; HYZAAR	5138069	AUG 11, 2009	U-3		
		5153197	OCT 06, 2009			
		5608075	MAR 04, 2014			
		5138069*	FEB 11, 2010			
		5153197*	APR 06, 2010	U-3		
		5608075*	SEP 04, 2014			
020716 001	HYDROCODONE BITARTRATE; VICOPROFEN	6348216	JUN 10, 2017		NP	AUG 01, 2003
021373 001	IBUPROFEN; CHILDREN'S ADVIL COL			PED		FEB 01, 2004
019700 001	KETOROLAC TROMETHAMINE; ACULAR	5599552	FEB 04, 2014	M-16		FEB 08, 2005
020811 001	KETOROLAC TROMETHAMINE; ACULAR PRESERVATIVE	5733950	OCT 03, 2008	M-16		FEB 08, 2005
021343 001	LEUPROLIDE ACETATE; ELIGARD	5739176	OCT 03, 2008			
		4938763	OCT 03, 2008			
		5278201	JAN 11, 2011			
		5324519	OCT 20, 2011			
020634 003	LEVOFLOXACIN; LEVAQUIN	5138069	AUG 11, 2009		I-305	FEB 02, 2003
020386 001	LOSARTAN POTASSIUM; COZAAR	5153197	OCT 06, 2009	U-3		
		5608075	MAR 04, 2014			
		5138069*	FEB 11, 2010			
		5153197*	APR 06, 2010	U-3		
		5608075*	SEP 04, 2014			
		5153197	OCT 06, 2009	U-3		
		5138069	AUG 11, 2009			
		5608075	MAR 04, 2014			
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		5153197*	APR 06, 2010	U-3		
020386 002	LOSARTAN POTASSIUM; COZAAR	5138069	AUG 11, 2009			
		5608075	MAR 04, 2014			
		5138069*	FEB 11, 2010			
		5153197*	APR 06, 2010	U-3		
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020386 003	LOSARTAN POTASSIUM; COZAAR	5138069 5153197 5608075 5138069*PED 5153197*PED 5608075*PED	AUG 11, 2009 OCT 06, 2009 MAR 04, 2014 FEB 11, 2010 APR 06, 2010 SEP 04, 2014	U-3 U-3		
019643 002	LOVASTATIN; MEVACOR				PED	AUG 14, 2005
019643 003	LOVASTATIN; MEVACOR				I-350	FEB 14, 2005
019643 004	LOVASTATIN; MEVACOR				PED	AUG 14, 2005
020922 001	MEQUINOL; SOLAGE				I-350	FEB 14, 2005
020357 001	METFORMIN HYDROCHLORIDE; GLUCOPHAGE	6353029	AUG 24, 2020		I-350	FEB 14, 2005
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020357 005	METFORMIN HYDROCHLORIDE; GLUCOPHAGE				PED	JUN 15, 2004
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021121 004	METHYLPHENIDATE HYDROCHLORIDE; CONCERTA	4519801 4612008 4783337 5082668	JUL 12, 2002 SEP 16, 2003 SEP 16, 2003 SEP 16, 2003	U-372	NP	AUG 01, 2003
020415 001	MIRTAZAPINE; REMERON				M-18	APR 09, 2005
020415 002	MIRTAZAPINE; REMERON				M-18	APR 09, 2005
020415 003	MIRTAZAPINE; REMERON				M-18	APR 09, 2005
019297 001	MITOXANTHONE HYDROCHLORIDE; NOVANTRONE				ODE	OCT 13, 2007
021260 001	MORPHINE SULFATE; AVINZA	6066339	NOV 25, 2017		NP	MAR 20, 2005
021260 002	MORPHINE SULFATE; AVINZA	6066339	NOV 25, 2017		NP	MAR 20, 2005
021260 003	MORPHINE SULFATE; AVINZA	6066339	NOV 25, 2017		NP	MAR 20, 2005

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021260 004	MORPHINE SULFATE; AVINZA				D-71	NOV 12, 2002
020076 004	NICOTINE; HABITROL				D-71	NOV 12, 2002
020076 005	NICOTINE; HABITROL				D-71	NOV 12, 2002
020076 006	NICOTINE; HABITROL				D-71	NOV 12, 2002
019810 001	OMEPRAZOLE; PRILOSEC	4636499*PED	NOV 30, 2005			
		6166213*PED	APR 19, 2019			
019810 002	OMEPRAZOLE; PRILOSEC	4636499*PED	NOV 30, 2005			
		6166213*PED	APR 19, 2019			
019810 003	OMEPRAZOLE; PRILOSEC	4636499*PED	NOV 30, 2005			
		6166213*PED	NOV 30, 2005			
020766 001	ORLISTAT; XENICAL	6166213*PED	APR 19, 2019			
021285 001	OXCARBAZEPINE; TRILEPTAL	4598089	JUN 18, 2009			
020553 001	OXYCODONE HYDROCHLORIDE; OXYCONTIN	4970075	AUG 29, 2006		NCE	JAN 14, 2005
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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020272 001	RISPERIDONE; RISPERDAL				M-15	MAR 03, 2005
020272 002	RISPERIDONE; RISPERDAL				M-15	MAR 03, 2005
020272 003	RISPERIDONE; RISPERDAL				M-15	MAR 03, 2005
020272 004	RISPERIDONE; RISPERDAL				M-15	MAR 03, 2005
020272 005	RISPERIDONE; RISPERDAL				M-15	MAR 03, 2005
020272 007	RISPERIDONE; RISPERDAL				M-15	MAR 03, 2005
020272 008	RISPERIDONE; RISPERDAL				M-15	MAR 03, 2005
020588 001	RISPERIDONE; RISPERDAL				M-15	MAR 03, 2005
021042 001	ROFECOXIB; VIOXX				M-15	MAR 03, 2005
021042 002	ROFECOXIB; VIOXX				M-15	MAR 03, 2005
021042 003	ROFECOXIB; VIOXX				M-15	MAR 03, 2005
021052 001	ROFECOXIB; VIOXX				M-15	MAR 03, 2005
021052 002	ROFECOXIB; VIOXX				M-15	MAR 03, 2005
020658 001	ROPINIROLE HYDROCHLORIDE; REQUIP	4452808	DEC 07, 2007		I-353	APR 11, 2005
020658 002	ROPINIROLE HYDROCHLORIDE; REQUIP	4452808	DEC 07, 2007		I-353	APR 11, 2005
020658 003	ROPINIROLE HYDROCHLORIDE; REQUIP	4452808	DEC 07, 2007		I-353	APR 11, 2005
020658 004	ROPINIROLE HYDROCHLORIDE; REQUIP	4452808	DEC 07, 2007		I-353	APR 11, 2005
020658 005	ROPINIROLE HYDROCHLORIDE; REQUIP	4452808	DEC 07, 2007		I-353	APR 11, 2005
020658 006	ROPINIROLE HYDROCHLORIDE; REQUIP	4452808	DEC 07, 2007		I-353	APR 11, 2005
020658 007	ROPINIROLE HYDROCHLORIDE; REQUIP	4452808	DEC 07, 2007		I-353	APR 11, 2005
020692 001	SALMETEROL XINAFOATE; SEREVENT	6352717	NOV 16, 2019		I-348	MAR 22, 2005
020828 001	SAQUINAVIR; FORTOVASE	6008228	JUN 06, 2015		NP	APR 04, 2005
021209 001	SECRETIN PORCINE SYNTHETIC; TRADE NAME NOT GIVEN				ODE	APR 04, 2009
019839 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
019839 002	SERTRALINE HYDROCHLORIDE; ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
019839 003	SERTRALINE HYDROCHLORIDE; ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
019839 004	SERTRALINE HYDROCHLORIDE; ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
019839 005	SERTRALINE HYDROCHLORIDE; ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
020478 001	SEVOFLURANE; ULTANE					
020632 001	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	4746680	JUN 11, 2007		M-17	MAR 30, 2004
020632 002	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	5436272	JUL 25, 2012	U-439		
020632 003	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	4746680	JUN 11, 2007	U-439		
020632 003	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	5436272	JUL 25, 2012	U-439		
020632 003	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	4746680	JUN 11, 2007	U-439		
020632 003	SIBUTRAMINE HYDROCHLORIDE; MERIDIA	5436272	JUL 25, 2012	U-439		
020677 001	SPARFLOXACIN; ZAGAM	4795751	FEB 04, 2010	U-160		
019785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	DEC 21, 2004			
019785 003	TECHNETIUM TC-99M SESTAMIBI KIT; MIRALUMA	4452774	DEC 21, 2004			
020791 001	TESTOSTERONE; TESTODERM TTS	6348210	NOV 10, 2019	U-440		
020785 001	THALIDOMIDE; THALOMID	6315720	OCT 23, 2020	U-442		
021228 001	TOLTERODINE TARTRATE; DETROL LA	5559269	NOV 05, 2013	U-318		
021228 002	TOLTERODINE TARTRATE; DETROL LA	5559269	NOV 05, 2013	U-318		

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020550 001	VALACYCLOVIR HYDROCHLORIDE; VALTREX	4957924 5879706 6107302	JUN 23, 2009 JAN 19, 2016 JAN 19, 2016			
020550 002	VALACYCLOVIR HYDROCHLORIDE; VALTREX	4957924 5879706 6107302	JUN 23, 2009 JAN 19, 2016 JAN 19, 2016			
020593 001	VALPROATE SODIUM; DEPAON	6294572	DEC 15, 2014		D-72	JAN 24, 2005
021036 001	ZANAMIVIR; RELENZA	6342515	DEC 21, 2018		U-438	
020789 001	ZONISAMIDE; ZONEGRAN					

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, 22ND 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

W EXCLUSIVITY ON THIS APPLICATION EXPIRING ON THIS DATE HAS BEEN WAIVED BY SPONSOR

REFERENCES

NEW DOSING SCHEDULE

D-71 EIGHT WEEK DOSING REGIMEN
D-72 INFORMATION REGARDING INCREASED RATE OF INFUSION FOR DEPACON

NEW INDICATION

I-348 LONG-TERM, TWICE-DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE
TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD (INCLUDING EMPHYSEMA AND CHRONIC
BRONCHITIS)
I-349 ACUTE CORONARY SYNDROME
I-350 TREATMENT OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA IN ADOLESCENT BOYS AND
GIRLS AT LEAST ONE YEAR POSTMENARCHAL, AGES 10 TO 17 YEARS, WITH A RECOMMENDED
DOSING RANGE OF 10 TO 40MG ONCE DAILY
I-351 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR ALL STRENGTHS
I-352 ANTICOAGULANT IN PATIENTS WITH OR AT RISK FOR HEPARIN-INDUCED THROMBOCYTOPENIA UNDERGOING
PERCUTANEOUS CORONARY INTERVENTIONS (PCI)
I-353 TREATMENT OF SIGNS AND SYMPTOMS OF RHEUMATOID ARTHRITIS

MISCELLANEOUS EXCLUSIVITY CODES

M-15 LONGER TERM EFFICACY INFORMATION FOR RISPERIDONE IN THE TREATMENT OF SCHIZOPHRENIA
M-16 CHANGE IN WORDING OF THE PEDIATRIC SECTION OF THE PACKAGE INSERT
M-17 INFORMATION REGARDING USE OF ULTANE IN PEDIATRIC PATIENTS WITH CONGENITAL HEART DISEASE
M-18 INFORMATION DENOTING THE EFFICACY OF REMERON IN MAINTAINING A RESPONSE IN PATIENTS WITH MAJOR
DEPRESSIVE DISORDER (MDD)

PATENT USE CODES

- U-438 TREATMENT/PREVENTION OF NEURODEGENERATIVE DISEASE
- U-439 TREATMENT OF OBESITY
- U-440 METHOD FOR TRANSDERMAL ADMINISTRATION OF A DRUG THROUGH NON-SCROTAL SKIN USING A
TRANSDERMAL DRUG DELIVERY DEVICE CONTAINING THE DRUG AND HAVING AN ADHESIVE
SURFACE
- U-441 METHOD OF TREATING MS BY ADMINISTERING COPAXONE
- U-442 METHOD FOR DELIVERING A DRUG TO A PATIENT IN NEED OF THE DRUG, WHILE AVOIDING THE
OCCURENCE OF AN ADVERSE SIDE EFFECT KNOWN OR SUSPECTED OF BEING CAUSED BY SAID
DRUG
- U-443 MANAGEMENT OF MODERATE TO SEVERE PAIN WHEN A CONTINUOUS, AROUND-THE-CLOCK ANALGESIC IS
NEEDED FOR AN EXTENDED PERIOD OF TIME

The logo of the American Society of Mechanical Engineers (ASME) is a circular emblem. It features a stylized mechanical component, possibly a valve or a pump, with a central shaft and a circular head. The emblem is set against a dark background and is surrounded by a circular border.

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

22nd EDITION

* 8392



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