CUMULATIVE SUPPLEMENT 3

JAN'93-MAR'93

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Approved drug products with therapeutic equivalence

Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

APPROVED DRUG PRODUCTS
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THERAPEUTIC EQUIVALENCE EVALUATIONS

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March 1993

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MARCH 1993

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, 13th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. 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.

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.)

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

Deletions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**DLT**> (DELETE) to the left of the line containing overstruck print. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

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 13th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 14th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

Products	Federal Register Reference
Nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Tranylcypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.3 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; or when an applicant name is changed to meet internal publication standards. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
BAKER CUMMINS PHARMACEUTICALS INC (BAKER CUMMINS)	BAKER NORTON PHARMACEUTICALS INC (BAKER NORTON)
RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV MCNEILAB (JOHNSON RW)	RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV ORTHO PHARMACEUTICAL CORP (JOHNSON RW)
HERBERT LABORATORIES DIV SMITH KLINE AND FRENCH CO (HERBERT)	ALLERGAN HERBERT DIV ALLERGAN INC (ALLERGAN HERBERT)

1.4 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

The U.S. Pharmacopeia (USP) periodically makes additions to or changes in monograph titles. Some of these additions or changes may affect dosage form terms listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (ADP). Instead of making the change in each affected product, the Cumulative Supplement (CS) will list applicable monograph title and dosage form additions or changes in this section. These will appear as soon as the modified USP monograph title is official. It is possible for these additions or changes to be listed in this section before all applicant holders have made labeling modifications.

The monograph title additions or changes shown below will remain in this section in each succeeding supplement of this edition. Once the next edition of the ADP is published, the products affected by the title additions or changes will be displayed with the new dosage form in the appropriate drug list. As notification to the reader, these monograph title additions or changes will also be listed in a special section of the ADP.

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

FORMER USP MONOGRAPH TITLE (FORMER ADP DOSAGE FORM; ROUTE)	NEW USP MONOGRAPH TITLE (NEW ADP DOSAGE FORM; ROUTE)

THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF MARCH 1993.

1.5 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 sections 505 and 507 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 1992) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1992	MAR 1993	JUN 1993	SEP 1993
DRUG PRODUCTS LISTED	9488			
SINGLE SOURCE	2245 (23.7%)			
MULTISOURCE	7243 (76.3%)			
THERAPEUTICALLY EQUIVALENT	6516 (68.6%)			
NOT THERAPEUTICALLY EQUIVALENT	577 (6.1%)			
EXCEPTIONS[1]	150 (1.6%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	477			

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL
ALLAY
/AA/ /LUCHEM/ /500MG;5MG/ /N89967/001/
/JAN/13,/1989/
AA NORTON HN 500MG;5MG N89907 001
JAN 13, 1989

TABLET; ORAL
ANEXSIA
AA BOEHRINGER MANNHEIM 500MG;5MG N89160 001
APR 23, 1987
/AA/ /SKCP/ /500MG;5MG/ /N89160/001/
/APR/23,/1987/

ANEXSIA 7.5/650
AA BOEHRINGER MANNHEIM 650MG;7.5MG N89725 001
SEP 30, 1987
/AA/ /SKCP/ /650MG;7.5MG/ /N89725/001/
/SEP/30,/1987/

HYDROCODONE BITARTRATE AND ACETAMINOPHEN
/AA/ /LUCHEM/ /500MG;5MG/ /N89696/001/
/APR/21,/1988/
AA NORTON HN 500MG;5MG N89696 001
APR 21, 1988

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HCL
/AB/ /BOLAR/ /100MG/ /N71382/001/
/JAN/21,/1987/
@ BOLAR 100MG N71382 001
JAN 21, 1987

AMINO ACIDS

INJECTABLE; INJECTION
NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER
BAXTER 15% N20107 001
FEB 05, 1993
/NOVAMINE/8.5%/
/KABIVITRUM/ /8.5%/ /N17957/002/
/AUG/09,/1982/
@ KABIVITRUM 8.5% N17957 002
AUG 09, 1982

AMINO ACIDS

INJECTABLE; INJECTION
TRAVASOL 10% IN PLASTIC CONTAINER
BAXTER 10% N18931 003
AUG 23, 1984
/10%/ /N18931/004/
/APR/27,/1988/
/TRAVASOL/10%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/
/BAXTER/ /10%/ /N18931/003/
/AUG/23,/1984/

TRAVASOL 5.5% IN PLASTIC CONTAINER
BAXTER 5.5% N18931 001
AUG 23, 1984
/TRAVASOL/5.5%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/
/BAXTER/ /5.5%/ /N18931/001/
/AUG/23,/1984/

TRAVASOL 8.5% IN PLASTIC CONTAINER
BAXTER 8.5% N18931 002
AUG 23, 1984
/TRAVASOL/8.5%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/
/BAXTER/ /8.5%/ /N18931/002/
/AUG/23,/1984/

AMINOCAPROIC ACID

INJECTABLE; INJECTION
AMINOCAPROIC ACID
/AP/ /LYPHOMED/ /250MG/ML/ /N70522/001/
/JUN/17,/1986/
@ LYPHOMED 250MG/ML N70522 001
JUN 17, 1986

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION
ELAVIL
/AP/ /MSD/ /10MG/ML/ /N12704/001/
AP ZENECA 10MG/ML N12704 001

TABLET; ORAL
ELAVIL
/AB/ /MSD/ /10MG/ /N12703/001/
/AB/ /+/ /25MG/ /N12703/003/
/AB/ /50MG/ /N12703/004/
/AB/ /75MG/ /N12703/005/
/AB/ /100MG/ /N12703/006/
/AB/ /150MG/ /N12703/007/

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
ELAVIL

AB	ZENECA	10MG	N12703 001
AB	+	25MG	N12703 003
AB		50MG	N12703 004
AB		75MG	N12703 005
AB		100MG	N12703 006
AB		150MG	N12703 007

AMOXICILLIN

CAPSULE; ORAL
/TRIMOX/

/AB/	/SQUIBB/	/250MG/	/N62098/001/
/AB/		/250MG/	/N62152/001/
/AB/		/500MG/	/N62098/002/
/AB/		/500MG/	/N62152/002/
	ə APOTHECON	250MG	N62098 001
	ə	250MG	N62152 001
	ə	500MG	N62098 002
	ə	500MG	N62152 002

POWDER FOR RECONSTITUTION; ORAL
/TRIMOX/

/AB/	/SQUIBB/	/125MG/5ML/	/N62099/001/
/AB/		/125MG/5ML/	/N62154/001/
/AB/		/250MG/5ML/	/N62099/002/
/AB/		/250MG/5ML/	/N62154/002/
	ə APOTHECON	125MG/5ML	N62099 001
	ə	125MG/5ML	N62154 001
	ə	250MG/5ML	N62099 002
	ə	250MG/5ML	N62154 002

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE ADIPATE; DEXTROAMPHETAMINE SULFATE

/CAPSULE;/ORAL/
/DELCOBESE/
/LEMMON/

/1.25MG;1.25MG;1.25MG;/ 1.25MG/		/N83564/001/
/2.5MG;2.5MG;2.5MG;2.5MG/		/N83564/002/
/3.75MG;3.75MG;3.75MG;/ 3.75MG/		/N83564/003/
/5MG;5MG;5MG;5MG/		/N83564/004/

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE ADIPATE; DEXTROAMPHETAMINE SULFATE

/CAPSULE;/ORAL/
/DELCOBESE/
ə LEMMON

1.25MG;1.25MG;1.25MG; 1.25MG		N83564 001
ə 2.5MG;2.5MG;2.5MG;2.5MG		N83564 002
ə 3.75MG;3.75MG;3.75MG; 3.75MG		N83564 003
ə 5MG;5MG;5MG;5MG		N83564 004

/TABLET;/ORAL/
/DELCOBESE/
/LEMMON/

/1.25MG;1.25MG;1.25MG;/ 1.25MG/		/N83563/004/
/2.5MG;2.5MG;2.5MG;2.5MG/		/N83563/003/
/3.75MG;3.75MG;3.75MG;/ 3.75MG/		/N83563/002/
/5MG;5MG;5MG;5MG/		/N83563/001/
ə LEMMON	1.25MG;1.25MG;1.25MG; 1.25MG	N83563 004
ə	2.5MG;2.5MG;2.5MG;2.5MG	N83563 003
ə	3.75MG;3.75MG;3.75MG; 3.75MG	N83563 002
ə	5MG;5MG;5MG;5MG	N83563 001

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM

/AP/	/LILLY/	/EQ 500MG BASE/VIAL/	/N62565/001/ /APR 04, 1985/
/AP/		/EQ 1GM BASE/VIAL/	/N62565/002/ /APR 04, 1985/
/AP/		/EQ 2GM BASE/VIAL/	/N62565/003/ /JUN 24, 1986/
	ə LILLY	EQ 500MG BASE/VIAL	N62565 001 APR 04, 1985
	ə	EQ 1GM BASE/VIAL	N62565 002 APR 04, 1985
	ə	EQ 2GM BASE/VIAL	N62565 003 JUN 24, 1986

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
/PRINCIPEN 250/

/AB/	/SQUIBB/	/EQ 250MG BASE/	/N50056/001/
/AB/		/EQ 250MG BASE/	/N62157/002/

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

/PRINCIPEN '250'/

	ə APOTHECON	EQ 250MG BASE	N50056 001
	ə	EQ 250MG BASE	N62157 002

/PRINCIPEN '500'/

/AB/	/SQUIBB/	/EQ 500MG BASE/	/N50056/002/
/AB/		/EQ 500MG BASE/	/N62157/001/
	ə APOTHECON	EQ 500MG BASE	N50056 002
	ə	EQ 500MG BASE	N62157 001

POWDER FOR RECONSTITUTION; ORAL

/PRINCIPEN '125'/

/AB/	/SQUIBB/	/EQ 125MG BASE/5ML/	/N60127/002/
/AB/		/EQ 125MG BASE/5ML/	/N62151/001/
	ə APOTHECON	EQ 125MG BASE/5ML	N60127 002
	ə	EQ 125MG BASE/5ML	N62151 001

/PRINCIPEN '250'/

/AB/	/SQUIBB/	/EQ 250MG BASE/5ML/	/N60127/001/
/AB/		/EQ 250MG BASE/5ML/	/N62151/002/
	ə APOTHECON	EQ 250MG BASE/5ML	N60127 001
	ə	EQ 250MG BASE/5ML	N62151 002

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

/CAPSULE;/ORAL/

/PRINCIPEN/W/PROBENECID/

/+//SQUIBB/		/EQ/389MG/BASE;111MG/	/N50488/001/
		/EQ/389MG/BASE;111MG/	/N62150/001/
	ə APOTHECON	EQ 389MG BASE;111MG	N50488 001
	ə	EQ 389MG BASE;111MG	N62150 001

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION

M.V.C. 9+3

AP	FUJISAWA	10MG/ML;0.006MG/ML;0.5UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 UNITS/ML;1 IU/ML	N18440 002 AUG 08, 1985
/AP/	/LYPHOMED/	/10MG/ML;0.006MG/ML;0.5UGM/ML;/ /1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;/ /0.4MG/ML;0.36MG/ML;0.3MG/ML;/ /330 UNITS/ML;1 IU/ML/	/N18440/002/ /AUG/08,/1985/

ASPIRIN; BUTALBITAL

TABLET; ORAL

AXOTAL

/+//ADRIA/		/650MG;50MG/	/N88305/001/ /OCT/13,/1983/
	+ SAVAGE	650MG;50MG	N88305 001 OCT 13, 1983

ATENOLOL

TABLET; ORAL

ATENOLOL

> ADD >	AB	MUTUAL PHARM	50MG	N73475 001 MAR 30, 1993
> ADD >	AB		100MG	N73476 001 MAR 30, 1993

AZLOCILLIN SODIUM

INJECTABLE; INJECTION

AZLIN

> DLT >	/MILES/	/EQ/2GM/BASE/VIAL/	/N62388/001/ /SEP/08,/1982/
> ADD >	ə MILES	EQ 2GM BASE/VIAL	N62388 001 SEP 08, 1982
> DLT >		/EQ/2GM/BASE/VIAL/	/N62417/001/ /OCT/12,/1982/
> ADD >	ə	EQ 2GM BASE/VIAL	N62417 001 OCT 12, 1982
> DLT >		/EQ/4GM/BASE/VIAL/	/N62388/003/ /SEP/08,/1982/
> ADD >	ə	EQ 4GM BASE/VIAL	N62388 003 SEP 08, 1982
> DLT >		/EQ/4GM/BASE/VIAL/	/N62417/003/ /OCT/12,/1982/
> ADD >	ə	EQ 4GM BASE/VIAL	N62417 003 OCT 12, 1982

BENTIROMIDE

SOLUTION; ORAL

CHYMEX

> DLT >	/ADRIA/	/500MG/7.5ML/	/N18366/001/ /DEC/29,/1983/
> ADD >	SAVAGE	500MG/7.5ML	N18366 001 DEC 29, 1983

BENZONATATE

CAPSULE; ORAL
BENZONATATE

AA	PHARMACAPS	100MG	N81297 001	JAN 29, 1993

TESSALON

AA	FOREST LABS	100MG	N11210 001

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL
BETAMETHASONE DIPROPIONATE

/AB/	/PHARMADERM/	/EQ 0.05% BASE/	/N19136/001/ /JUN/26,/1984/
	@ PHARMADERM	EQ 0.05% BASE	N19136 001 JUN 26, 1984

LOTION; TOPICAL
BETAMETHASONE DIPROPIONATE

/AB/	/PHARMADERM/	/EQ 0.05% BASE/	/N70274/001/ /AUG/12,/1985/
	@ PHARMADERM	EQ 0.05% BASE	N70274 001 AUG 12, 1985

BETAMETHASONE VALERATE

CREAM; TOPICAL
BETAMETHASONE VALERATE

/AB/	/PHARMADERM/	/EQ 0.1% BASE/	/N18860/002/ /AUG/31,/1983/
	@ PHARMADERM	EQ 0.1% BASE	N18860 002 AUG 31, 1983

LOTION; TOPICAL
BETAMETHASONE VALERATE

/AB/	/PHARMADERM/	/EQ 0.1% BASE/	/N18870/001/ /AUG/31,/1983/
	@ PHARMADERM	EQ 0.1% BASE	N18870 001 AUG 31, 1983

OINTMENT; TOPICAL
BETAMETHASONE VALERATE

/AB/	/PHARMADERM/	/EQ 0.1% BASE/	/N18864/001/ /AUG/31,/1983/
	@ PHARMADERM	EQ 0.1% BASE	N18864 001 AUG 31, 1983

> ADD > BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

> ADD > TABLET; ORAL
> ADD > ZIAC

> ADD >	+ LEDERLE	10MG;6.25MG	N20186 002 MAR 26, 1993
> ADD >		2.5MG;6.25MG	N20186 003 MAR 26, 1993
> ADD >		5MG;6.25MG	N20186 001 MAR 26, 1993

BROMPHENIRAMINE MALEATE

TABLET; ORAL
BROMPHENIRAMINE MALEATE

/AA/	/ZENITH/	/4MG/		/N84351/001/
	@ ZENITH	4MG		N84351 001

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION
CALCIUM GLUCEPTATE

/AP/	/LYPHOMED/	/EQ 90MG CALCIUM/5ML/		/N89373/001/ /APR/30,/1987/
	@ LYPHOMED	EQ 90MG CALCIUM/5ML		N89373 001 APR 30, 1987

CARISOPRODOL

TABLET; ORAL
/RELA/

/AA/	/SCHERING/	/350MG/		/N12155/001/
	@ SCHERING	350MG		N12155 001

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OPTIPRESS

> DLT >	/BURROUGHS/WELLCOME/	/1%/		/N19972/001/ /MAY/23,/1990/
> DLT >				
> ADD >	OTSUKA	1%		N19972 001 MAY 23, 1990
> ADD >				

CEFOXITIN SODIUM

INJECTABLE; INJECTION
MEFOXIN IN PLASTIC CONTAINER
MERCK — EQ 20MG BASE/ML — N63182 001 JAN 25, 1993
EQ 40MG BASE/ML — N63182 002 JAN 25, 1993

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFIZOX
> ADD > FUJISAWA — EQ 10GM BASE/VIAL — N50560 005 MAR 19, 1993
> ADD >

CEFUROXIME SODIUM

INJECTABLE; INJECTION
CEFUROXIME
AP MARSAM — EQ 750MG BASE/VIAL — N64035 001 FEB 26, 1993
AP — EQ 1.5GM BASE/VIAL — N64035 002 FEB 26, 1993
AP — EQ 7.5GM BASE/VIAL — N64036 001 FEB 26, 1993

KEFUROX
AP LILLY — EQ 7.5GM BASE/VIAL — N62591 003 DEC 17, 1987

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
LIBRIUM
> DLT > /AB/ /ROCHE/ — 5MG — N12249/002
> DLT > /AB/ — 10MG — N12249/001
> DLT > /AB//+/ — 25MG — N12249/003
> DLT > /AB/ — 25MG — N85475/001
> ADD > AB + ROCHE — 25MG — N85475 001
> ADD > ∂ — 5MG — N12249 002
> ADD > ∂ — 10MG — N12249 001
> ADD > ∂ — 25MG — N12249 003

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL
/AP/ /LYPHOMED/ — 25MG/ML — N84911/001
∂ LYPHOMED — 25MG/ML — N84911 001

CHLORTHALIDONE; METOPROLOL TARTRATE

> DLT > /CAPSULE;/ORAL/
> DLT > /LOPRESSIDONE/
> DLT > /+//CIBA/ — /25MG;200MG/ — /N19451/002/ /DEC/31,/1987/
> DLT > — /25MG;100MG/ — /N19451/001/ /DEC/31,/1987/
> ADD > ∂ CIBA — 25MG;100MG — N19451 001 DEC 31, 1987
> ADD > ∂ — 25MG;200MG — N19451 002 DEC 31, 1987
> ADD >

CLADRIBINE

INJECTABLE; INJECTION
LEUSTATIN
+ JOHNSON RW — 1MG/ML — N20229 001 FEB 26, 1993

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL
CLEOCIN
> ADD > AB + UPJOHN — EQ 75MG BASE — N50162 001
> DLT > /AB//+/ — /EQ 75MG BASE/ — /N61809/001/
> ADD > AB + CIBA — EQ 150MG BASE — N50162 002
> DLT > /AB//+/ — /EQ 150MG BASE/ — /N61809/002/
> ADD > ∂ — EQ 75MG BASE — N61809 001
> ADD > ∂ — EQ 150MG BASE — N61809 002

CLOTRIMAZOLE

> DLT > /CREAM;/VAGINAL/
> DLT > /GYNE-LOTRIMIN/
> DLT > /B†/ /SCHERING/ — /1%/ — /N18052/001/
> DLT > /MYCELEX-G/
> DLT > /B†/ /MILES/ — /1%/ — /N18230/001/

> DLT > /TABLET;/VAGINAL/
> DLT > /GYNE-LOTRIMIN/
> DLT > /B†/ /SCHERING/ — /100MG/ — /N17717/001/
> DLT > /MYCELEX-G/
> DLT > /B†/ /MILES/ — /100MG/ — /N18182/001/

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

/BP/	/HEATHER/	/25MG/	/N85736/001/	
	@ HEATHER	25MG	N85736 001	

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN

/AP/	/FUJISAWA/	/1MG/ML/	/N83075/001/	
	@ FUJISAWA	1MG/ML	N83075 001	

CYCLOBENZAPRINE

TABLET; ORAL
CYCLOBENZAPRINE HCL

AB	INVAMED	10MG	N73683 001	
			FEB 26, 1993	

DESIPRAMINE HYDROCHLORIDE

>DLT>	/CAPSULE;ORAL/			
>DLT>	/PERTOFRANE/			
>DLT>	/+//RHONE/POULENC/RORER/	/50MG/	/N13621/002/	
>DLT>		/25MG/	/N13621/001/	
>ADD>	@ RHONE POULENC RORER	25MG	N13621 001	
>ADD>	@	50MG	N13621 002	

DESMOPRESSIN ACETATE

>ADD>	SPRAY, METERED; NASAL			
>ADD>	DDAVP			
>ADD>	RHONE POULENC RORER	0.01MG/INH	N17922 002	
>ADD>			FEB 06, 1989	

DESOXYCORTICOSTERONE PIVALATE

>DLT>	/INJECTABLE;INJECTION/			
>DLT>	/PERCORTEN/			
>DLT>	/CIBA/	/25MG/ML/	/N08822/001/	
>ADD>	@ CIBA	25MG/ML	N08822 001	

DEXAMETHASONE

SOLUTION; ORAL
/DEXAMETHASONE/

	/ROXANE/	/0.5MG/5ML/	/N88248/001/	
			/SEP/01,/1983/	
	@ ROXANE	0.5MG/5ML	N88248 001	
			SEP 01, 1983	

TABLET; ORAL
DECADRON

>ADD>	AB	MSD	0.5MG	N11664 001
>ADD>	AB	+	0.75MG	N11664 002
>ADD>	AB		1.5MG	N11664 003
>ADD>	AB		4MG	N11664 005
>DLT>	/BP/		/0.5MG/	/N11664/001/
>DLT>	/BP/+/		/0.75MG/	/N11664/002/
>DLT>	/BP/		/1.5MG/	/N11664/003/
>DLT>	/BP/		/4MG/	/N11664/005/

DEXAMETHASONE

>ADD>	AB	ROXANE	0.5MG	N84611 001
>ADD>	AB		0.75MG	N84613 001
>ADD>	AB		1.5MG	N84610 001
>ADD>	AB		4MG	N84612 001
>DLT>	/BP/		/0.5MG/	/N84611/001/
>DLT>	/BP/		/0.75MG/	/N84613/001/
>DLT>	/BP/		/1.5MG/	/N84610/001/
>DLT>	/BP/		/4MG/	/N84612/001/

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL
/DEXAMPEX/

/AA/	/LEMMON/	/5MG/	/N83735/001/	
/AA/		/10MG/	/N83735/002/	
	@ LEMMON	5MG	N83735 001	
	@	10MG	N83735 002	

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM

AP	MARSAM	5MG/ML	N72370 001
			JAN 29, 1993
AP		5MG/ML	N72371 001
			JAN 29, 1993
AP		5MG/ML	N72397 001
			JAN 29, 1993

DIAZEPAM

TABLET; ORAL
DIAZEPAM

/AB/	/ZENITH/	/2MG/	/N70360/001/ /SEP/04,/1985/	
/AB/		/5MG/	/N70361/001/ /SEP/04,/1985/	
	@ ZENITH	2MG	N70360 001 SEP 04, 1985	
	@	5MG	N70361 001 SEP 04, 1985	

DIAZOXIDE

CAPSULE; ORAL
PROGLYCEM

	+ BAKER NORTON	50MG	N17425 001	
/+//MEDCL/MKTG/		/50MG/	/N17425/001/	

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
VOLTAREN

>_DLT_>	/CIBA/	/0.1%/	/N20037/001/ /MAR/28,/1991/	
>_ADD_>	CIBA VISION	0.1%	N20037 001 MAR 28, 1991	

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

>_ADD_>	AB	APOTHECON 30MG	N74051 001 MAR 31, 1993	
>_ADD_>	AB	60MG	N74051 002 MAR 31, 1993	
>_ADD_>	AB	90MG	N74051 003 MAR 31, 1993	
>_ADD_>	AB	120MG	N74051 004 MAR 31, 1993	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL

/AP/	/LYPHOMED/	/40MG/ML/	/N70012/001/ /JUN/12,/1985/	
	@ LYPHOMED	40MG/ML	N70012 001 JUN 12, 1985	

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL

/AP/	/SMITH/NEPHEW/SOLOPAK/	2.5MG/ML/	/N71754/001/ /SEP/06,/1988/	
/AP/		/2.5MG/ML/	/N71755/001/ /SEP/06,/1988/	
AP	SOLOPAK	2.5MG/ML	N71754 001 SEP 06, 1988	
AP		2.5MG/ML	N71755 001 SEP 06, 1988	

ENOXACIN

TABLET; ORAL
PENETREX

>_DLT_>	/+//PARKE/DAVIS/	/400MG/	/N19616/005/ /DEC/31,/1991/	
>_DLT_>		/200MG/	/N19616/004/ /DEC/31,/1991/	
>_ADD_>	+ RHONE POULENC RORER	400MG	N19616 005 DEC 31, 1991	
>_ADD_>		200MG	N19616 004 DEC 31, 1991	

>_ADD_> ENOXAPARIN SODIUM

INJECTABLE; INJECTION
LOVENOX

>_ADD_>	RHONE POULENC RORER	30MG/0.3ML	N20164 001 MAR 29, 1993

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL AND EPINEPHRINE

AP	STERLING WINTHROP	0.01MG/ML;2%	N40057 002 FEB 26, 1993
AP		0.02MG/ML;2%	N40057 001 FEB 26, 1993

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
HYDROGENATED ERGOT ALKALOIDS

/AA/	/ZENITH/	/0.5MG/	/N87186/001/
@ ZENITH		0.5MG	N87186 001

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL
ERGOMAR

AA	FISONS	2MG	N87693 001 FEB 24, 1983
/A/		/2MG/	/N87693/001/ /FEB/24,/1983/

ERYTHROMYCIN

GEL; TOPICAL
ERYGEL

/AT/	/HERBERT/	/2%/	/N50617/001/ /OCT/21,/1987/
AT +	HERBERT	2%	N50617 001 OCT 21, 1987

ERYTHROMYCIN

AT	STIEFEL	2%	N63211 001 JAN 29, 1993

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
PROZAC

>ADD>	LILLY	EQ 10MG BASE	N18936 006 DEC 23, 1992
>ADD>			

GADODIAMIDE

INJECTABLE; INJECTION
OMNISCAN

	STERLING WINTHROP	287MG/ML	N20123 001 JAN 08, 1993

GEMFIBROZIL

CAPSULE; ORAL
GEMFIBROZIL

AB	MYLAN	300MG	N73466 001 JAN 25, 1993
AB	PUREPAC	300MG	N72929 001 JAN 29, 1993

LOPID

AB +	PARKE DAVIS	300MG	N18422 002

GENTAMICIN SULFATE

CREAM; TOPICAL
GENTAMICIN SULFATE

/AT/	/PHARMADERM/	/EQ 1MG BASE/GM/	/N62530/001/ /JUL/05,/1984/
@ PHARMADERM		EQ 1MG BASE/GM	N62530 001 JUL 05, 1984

GLUTETHIMIDE

>DLT>	/CAPSULE;ORAL/		
>DLT>	/DORIDEN/		
>DLT>	/RHONE/POULENC/RORER//500MG/		/N09519/008/
>ADD>	@ RHONE POULENC RORER	500MG	N09519 008

HALOPERIDOL LACTATE

CONCENTRATE; ORAL
HALOPERIDOL

AA	PHARM ASSOC	EQ 2MG BASE/ML	N73037 001 FEB 26, 1993

INJECTABLE; INJECTION
HALOPERIDOL

AP	MARSAM	EQ 5MG BASE/ML	N72516 001 FEB 25, 1993
AP		EQ 5MG BASE/ML	N72517 001 FEB 25, 1993

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL			
/AP/	/SMITH/NEPHEW/SOLOPAK/	/EQ 5MG BASE/ML/	/N70801/001/ /DEC/14,/1987/
/AP/		/EQ 5MG BASE/ML/	/N70864/001/ /DEC/14,/1987/
AP	SOLOPAK	EQ 5MG BASE/ML	N70801 001 DEC 14, 1987
AP		EQ 5MG BASE/ML	N70864 001 DEC 14, 1987

HEXACHLOROPHENE

SOLUTION; TOPICAL

> DLT >	/DIAL/			
> DLT >	/AT/	/ARMOUR/DIAL/	/0.25%/	/N17421/002/
> ADD >		@ DIAL	0.25%	N17421 002
	GERMA-MEDICA "MG"			
> DLT >	/AT/	/HUNTINGTON/	/0.25%/	/N17412/002/
> ADD >		HUNTINGTON	0.25%	N17412 002

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE				
/AT/	/BIOCRAFT/	/0.5%/	/N80400/002/	
/AT/		/1%/	/N80400/003/	
/AT/		/2.5%/	/N80400/004/	
	@ BIOCRAFT	0.5%	N80400 002	
	@	1%	N80400 003	
	@	2.5%	N80400 004	
/AT/	/PHARMADERM/	/1%/	/N88845/001/ /FEB/27,/1986/	
	@ PHARMADERM	1%	N88845 001 FEB 27, 1986	

LOTION; TOPICAL

ACTICORT				
> ADD > AT		BAKER NORTON	1%	N86535 001
> DLT >	/AT/	/KEY/PHARMS/	/1%/	/N86535/001/

IBUPROFEN

TABLET; ORAL

IBUPROFEN				
AB		NORTON HN	400MG	N71145 001 SEP 23, 1986
AB			600MG	N71146 001 SEP 23, 1986
AB			800MG	N71769 001 MAY 08, 1987
	/IFEN/			
/AB/	/LUCHEM/		/400MG/	/N71145/001/ /SEP/23,/1986/
/AB/			/600MG/	/N71146/001/ /SEP/23,/1986/
/AB/			/800MG/	/N71769/001/ /MAY/08,/1987/

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL				
/AN/	/ASTRA/		/0.125%/	/N87938/001/ /NOV/15,/1982/
			/0.062%/	/N87937/001/ /NOV/15,/1982/
	@ ASTRA		0.062%	N87937 001 NOV 15, 1982
	@		0.125%	N87938 001 NOV 15, 1982

ISOFLURANE

LIQUID; INHALATION

FORANE				
AN	+	ANAQUEST	99.9%	N17624 001
ISOFLURANE				
AN		ABBOTT	99.9%	N74097 001 JAN 25, 1993

ISOSORBIDE DINITRATE

TABLET; ORAL

SORBITRATE				
/AB/	/ICI/		/20MG/	/N86405/002/ /AUG/21,/1990/
/AB/			/30MG/	/N88124/001/ /AUG/21,/1990/
/AB/			/40MG/	/N88125/001/ /AUG/21,/1990/

ISOSORBIDE DINITRATE

TABLET; ORAL
SORBITRATE

AB	ZENECA	20MG	N86405 002 AUG 21, 1990
AB		30MG	N88124 001 AUG 21, 1990
AB		40MG	N88125 001 AUG 21, 1990

KANAMYCIN SULFATE

INJECTABLE; INJECTION
/KLEMCIL/

/AP/	/SMITHKLINE/BEECHAM/	/EQ 75MG BASE/2ML/	/N62170/001/
/AP/		/EQ 500MG BASE/2ML/	/N62170/002/
/AP/		/EQ 1GM BASE/3ML/	/N62170/003/
	ə SMITHKLINE BEECHAM	EQ 75MG BASE/2ML	N62170 001
	ə	EQ 500MG BASE/2ML	N62170 002
	ə	EQ 1GM BASE/3ML	N62170 003

KETOPROFEN

CAPSULE; ORAL
KETOPROFEN

AB	LEDERLE	25MG	N74014 001 JAN 29, 1993
AB		50MG	N74014 002 JAN 29, 1993
AB		75MG	N74014 003 JAN 29, 1993

LACTULOSE

> DLT >	/SOLUTION;/ORAL/			
> DLT >	/CEPHULAC/			
> DLT >	/AA/ /MERRELL/DOW/	/10GM/15ML/	/N17657/001/	
> DLT >	/ENULOSE/			
> DLT >	/AA/ /BARRE/	/10GM/15ML/	/N71548/001/ /AUG/15,/1988/	
> DLT >				
> DLT >	/GENERLAC/			
> DLT >	/AA/ /PHARM/BASICS/	/10GM/15ML/	/N71842/001/ /SEP/27,/1988/	
> DLT >				
> DLT >	/LACTULOSE/			
> DLT >	/SOLVAY/	/10GM/15ML/	/N17906/001/	
> DLT >	/PORTALAC/			
> DLT >	/AA/ /SOLVAY/	/10GM/15ML/	/N72374/001/ /MAR/22,/1989/	
> DLT >				

LACTULOSE

> ADD >	SOLUTION; ORAL, RECTAL			
> ADD >	CEPHULAC			
> ADD >	AA MERRELL DOW	10GM/15ML	N17657 001	
> ADD >	ENULOSE			
> ADD >	AA BARRE	10GM/15ML	N71548 001 AUG 15, 1988	
> ADD >				
> ADD >	GENERLAC			
> ADD >	AA PHARM BASICS	10GM/15ML	N71842 001 SEP 27, 1988	
> ADD >				
> ADD >	LACTULOSE			
> ADD >	ə SOLVAY	10GM/15ML	N17906 001	
> ADD >	PORTALAC			
> ADD >	AA SOLVAY	10GM/15ML	N72374 001 MAR 22, 1989	
> ADD >				

LEUCOVORIN CALCIUM

TABLET; ORAL
LEUCOVORIN CALCIUM

AB	LEDERLE	EQ 10MG BASE	N71962 001 NOV 19, 1987
AB	+	EQ 15MG BASE	N71104 001 MAR 04, 1987
AB	ROXANE	EQ 5MG BASE	N72733 001 FEB 22, 1993
AB		EQ 10MG BASE	N72734 001 FEB 22, 1993
AB		EQ 15MG BASE	N72735 001 FEB 22, 1993
AB		EQ 25MG BASE	N72736 001 FEB 22, 1993

LIDOCAINE

> DLT >	/SUPPOSITORY;/RECTAL/		
> DLT >	/XYLOCAINE/		
> DLT >	/ASTRA/	/100MG/	/N13077/001/
> ADD >	ə ASTRA	100MG	N13077 001

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL

/AP/	/LYPHOMED/	/1%/	/N86761/001/
/AP/		/2%/	/N86761/002/
	ə LYPHOMED	1%	N86761 001
	ə	2%	N86761 002

LIOTRIX (T4;T3)

TABLET; ORAL

THYROLAR-0.25		
FOREST LABS	0.0125MG;0.0031MG	N16807 001
/RHONE/POULENC/RORER//0.0125MG;0.0031MG/		/N16807/001/
THYROLAR-0.5		
FOREST LABS	0.025MG;0.00625MG	N16807 005
/RHONE/POULENC/RORER//0.025MG;0.00625MG/		/N16807/005/
THYROLAR-1		
FOREST LABS	0.05MG;0.0125MG	N16807 004
/RHONE/POULENC/RORER//0.05MG;0.0125MG/		/N16807/004/
THYROLAR-2		
FOREST LABS	0.1MG;0.025MG	N16807 002
/RHONE/POULENC/RORER//0.1MG;0.025MG/		/N16807/002/
THYROLAR-3		
+ FOREST LABS	0.15MG;0.0375MG	N16807 003
/+//RHONE/POULENC/RORER//0.15MG;0.0375MG/		/N16807/003/
THYROLAR-5		
@ FOREST LABS	0.25MG;0.0625MG	N16807 006
/@/RHONE/POULENC/RORER//0.25MG;0.0625MG/		/N16807/006/

MANGANESE SULFATE

INJECTABLE; INJECTION

MANGANESE SULFATE		
FUJISAWA	EQ 0.1MG MANGANESE/ML	N19228 001
		MAY 05, 1987
/LYPHOMED/	/EQ/0.1MG/MANGANESE/ML/	/N19228/001/
		/MAY/05,/1987/

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

	/METHAMPEX/		
/AA/	/LEMMON/	/10MG/	/N83889/001/
@ LEMMON		10MG	N83889 001
	METHAMPHETAMINE HCL		
/AA/	/REXAR/	/10MG/	/N84931/002/
REXAR		10MG	N84931 002

METHOTREXATE SODIUM

INJECTABLE; INJECTION

	METHOTREXATE SODIUM		
/AP/	/LYPHOMED/	/EQ 25MG BASE/ML/	/N89263/001/
			/JUN/13,/1986/
@ LYPHOMED		EQ 25MG BASE/ML	N89263 001
			JUN 13, 1986

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION

	METHYLDOPATE HCL		
/AP/	/LYPHOMED/	/50MG/ML/	/N70652/001/
			/JUN/03,/1986/
@ LYPHOMED		50MG/ML	N70652 001
			JUN 03, 1986

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

	METHYLPREDNISOLONE SODIUM SUCCINATE		
/AP/	/LYPHOMED/	/EQ 40MG BASE/VIAL/	/N89143/001/
			/MAR/28,/1986/
/AP/		/EQ 125MG BASE/VIAL/	/N89144/001/
			/MAR/28,/1986/
/AP/		/EQ 500MG BASE/VIAL/	/N89187/001/
			/MAR/28,/1986/
/AP/		/EQ 1GM BASE/VIAL/	/N89189/001/
			/MAR/28,/1986/
@ LYPHOMED		EQ 40MG BASE/VIAL	N89143 001
			MAR 28, 1986
@		EQ 125MG BASE/VIAL	N89144 001
			MAR 28, 1986
@		EQ 500MG BASE/VIAL	N89187 001
			MAR 28, 1986
@		EQ 1GM BASE/VIAL	N89189 001
			MAR 28, 1986

METRONIDAZOLE

TABLET; ORAL

	/SATRIC/		
/AB/	/SAVAGE/	/250MG/	/N70029/001/
			/MAR/19,/1985/
/AB/		/500MG/	/N70731/001/
			/JUN/08,/1987/
@ SAVAGE		250MG	N70029 001
			MAR 19, 1985
@		500MG	N70731 001
			JUN 08, 1987

MICONAZOLE NITRATE

>DLT>	/CREAM;/VAGINAL/		
>DLT>	/MONISTAT/7/		
>DLT>	/JOHNSON/RW/	/2%/	/N17456/001/

MICONAZOLE NITRATE

>_DLT_>	/SUPPOSITORY;/VAGINAL/			
>_DLT_>	/MONISTAT/7/			
>_DLT_>	/JOHNSON/RW/	/100MG/	/N18520/001/ /MAR/15,/1982/	
>_DLT_>				

MORICIZINE HYDROCHLORIDE

TABLET; ORAL
ETHMOZINE

>_DLT_>	/DUPONT/	/200MG/	/N19753/001/ /JUN/19,/1990/	
>_DLT_>				
>_DLT_>		/250MG/	/N19753/002/ /JUN/19,/1990/	
>_DLT_>				
>_DLT_>		/300MG/	/N19753/003/ /JUN/19,/1990/	
>_DLT_>				
>_ADD_>	ROBERTS	200MG	N19753 001 JUN 19, 1990	
>_ADD_>				
>_ADD_>		250MG	N19753 002 JUN 19, 1990	
>_ADD_>				
>_ADD_>		300MG	N19753 003 JUN 19, 1990	
>_ADD_>				

NABILONE

	/CAPSULE;/ORAL/			
	/CESAMET/			
	/+//LILLY/	/1MG/	/N18677/001/ /DEC/26,/1985/	
	@ LILLY	1MG	N18677 001 DEC 26, 1985	

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HYDROCHLORIDE

>_ADD_>	ABBOTT	1.5MG/ML	N20200 001 MAR 12, 1993
>_ADD_>			

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL

/AP/	/LYPHOMED/	/0.02MG/ML/	/N70661/001/ /NOV/17,/1986/	
	@ LYPHOMED	0.02MG/ML	N70661 001 NOV 17, 1986	

NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE

/AO/	/LYPHOMED/	/100MG/ML/	/N88296/001/ /OCT/03,/1983/	
/AO/		/200MG/ML/	/N88317/001/ /OCT/14,/1983/	
	@ LYPHOMED	100MG/ML	N88290 001 OCT 03, 1983	
	@	200MG/ML	N88317 001 OCT 14, 1983	

NIACIN

TABLET; ORAL
NIACIN

/AA/	/ZENITH/	/500MG/	/N83180/001/	
	@ ZENITH	500MG	N83180 001	

NITROFURANTOIN

TABLET; ORAL
NITROFURANTOIN

/AB/	/ZENITH/	/50MG/	/N80078/002/	
/AB/		/100MG/	/N80078/001/	
	@ ZENITH	50MG	N80078 002	
	@	100MG	N80078 001	

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
NITROFURANTOIN

AB	ZENITH	50MG	N73671 001 JAN 28, 1993
AB		100MG	N73652 001 JAN 28, 1993

NYSTATIN

CREAM; TOPICAL
NYSTATIN

AT	TARO	100,000 UNITS/GM	N64022 001 JAN 29, 1993

NYSTATIN

SUSPENSION; ORAL
NYSTATIN

/AA/	/PHARMADERM/	/100,000 UNITS/ML/	/N62518/001/	
			/JUL/06/1984/	
	ə PHARMADERM	100,000 UNITS/ML	N62518 001	
			JUL 06, 1984	

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN-TRIAMCINOLONE ACETONIDE

/AT/	/PHARMADERM/	/100,000 UNITS/GM;0.1%/	/N62596/001/	
			/OCT/08/1985/	
	ə PHARMADERM	100,000 UNITS/GM;0.1%	N62596 001	
			OCT 08, 1985	

OINTMENT; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

>ADD>	AT	TARO	100,000 UNITS/GM;0.1%	N63305 001	
>ADD>				MAR 29, 1993	

OXPRENOLOL HYDROCHLORIDE

>DLT>	/CAPSULE;ORAL/				
>DLT>	/TRASICOR/				
>DLT>	/+//CIBA/	/160MG/		/N18166/004/	
>DLT>				/DEC/28/1983/	
>DLT>		/20MG/		/N18166/001/	
>DLT>				/DEC/28/1983/	
>DLT>		/40MG/		/N18166/002/	
>DLT>				/DEC/28/1983/	
>DLT>		/80MG/		/N18166/003/	
>DLT>				/DEC/28/1983/	
>ADD>	ə CIBA	20MG		N18166 001	
>ADD>				DEC 28, 1983	
>ADD>	ə	40MG		N18166 002	
>ADD>				DEC 28, 1983	
>ADD>	ə	80MG		N18166 003	
>ADD>				DEC 28, 1983	
>ADD>	ə	160MG		N18166 004	
>ADD>				DEC 28, 1983	

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN

/AA/	/BIOCRAFT/	/200,000 UNITS/5ML/	/N60307/002/	
	BIOCRAFT	200,000 UNITS/5ML	N60307 002	
	/PENTIDS'200'/			
/AA/	/SQUIBB/	/200,000 UNITS/5ML/	/N62149/001/	
	ə APOTHECON	200,000 UNITS/5ML	N62149 001	
	/PENTIDS'400'/			
/AA/	/SQUIBB/	/400,000 UNITS/5ML/	/N62149/002/	
	ə APOTHECON	400,000 UNITS/5ML	N62149 002	

TABLET; ORAL
PENICILLIN G POTASSIUM

	ə APOTHECON	250,000 UNITS	N60392 003	
/AB/	/SQUIBB/	/250,000 UNITS/	/N60392/003/	
	/PENTIDS'200'/			
/AB/	/SQUIBB/	/200,000 UNITS/	/N62155/001/	
	ə APOTHECON	200,000 UNITS	N62155 001	
	/PENTIDS'250'/			
/AB/	/SQUIBB/	/250,000 UNITS/	/N62155/002/	
	ə APOTHECON	250,000 UNITS	N62155 002	
	/PENTIDS'400'/			
/AB/	/SQUIBB/	/400,000 UNITS/	/N60392/004/	
/AB/		/400,000 UNITS/	/N62155/003/	
	ə APOTHECON	400,000 UNITS	N60392 004	
	ə	400,000 UNITS	N62155 003	
	/PENTIDS'800'/			
/AB/	/SQUIBB/	/800,000 UNITS/	/N60392/005/	
/AB/		/800,000 UNITS/	/N62155/004/	
	ə APOTHECON	800,000 UNITS	N60392 005	
	ə	800,000 UNITS	N62155 004	

PENICILLIN G PROCAINE

INJECTABLE; INJECTION
/DURACILLIN A.S./

/AP/	/LILLY/	/300,000 UNITS/ML/	/N60093/001/	
	ə LILLY	300,000 UNITS/ML	N60093 001	

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
/VEETIDS'125'/

/AA/	/SQUIBB/	/EQ 125MG BASE/5ML/	/N61206/001/	
>DLT>/AA/		/EQ 125MG BASE/5ML/	/N62153/001/	
	ə APOTHECON	EQ 125MG BASE/5ML	N61206 001	
>ADD>	ə	EQ 125MG BASE/5ML	N62153 001	

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

VEETIDS 125

/AA/	/SQUIBB/	/EQ 250MG BASE/5ML/	/N61206/002/		
> DLT >/AA/		/EQ 250MG BASE/5ML/	/N62153/002/		
	@ APOTHECON	EQ 250MG BASE/5ML	N61206 002		
> ADD >	@	EQ 250MG BASE/5ML	N62153 002		

TABLET; ORAL

VEETIDS 125

/AB/	/SQUIBB/	/EQ 250MG BASE/	/N61164/001/
/AB/		/EQ 250MG BASE/	/N62156/002/
	@ APOTHECON	EQ 250MG BASE	N61164 001
	@	EQ 250MG BASE	N62156 002

VEETIDS 500

/AB/	/SQUIBB/	/EQ 500MG BASE/	/N61164/002/
/AB/		/EQ 500MG BASE/	/N62156/001/
	@ APOTHECON	EQ 500MG BASE	N61164 002
	@	EQ 500MG BASE	N62156 001

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

/AA/	/ZENITH/	/30MG/	/N86329/001/
	@ ZENITH	30MG	N86329 001

PHENYLBUTAZONE

CAPSULE; ORAL

PHENYLBUTAZONE

> DLT >/AB/	/CHELSEA/	/100MG/	/N87756/001/			
> DLT >			/DEC/17,/1982/			
> ADD > B*	CHELSEA	100MG	N87756 001	> DLT >	/BC/	/ADRIA/
> ADD >			DEC 17, 1982	> ADD >	BC	SAVAGE

PINDOLOL

TABLET; ORAL

PINDOLOL

> ADD > AB	GENEVA	5MG	N73608 001	> DLT >	
> ADD >			MAR 29, 1993	> DLT >	
> ADD > AB		10MG	N73609 001	> ADD >	+ BRISTOL MYERS SQUIBB 40MG
> ADD >			MAR 29, 1993	> ADD >	
AB	ZENITH	5MG	N73687 001	> ADD >	20MG
			FEB 26, 1993	> ADD >	
AB		10MG	N73687 002		
			FEB 26, 1993		

PIROXICAM

CAPSULE; ORAL

PIROXICAM

> ADD > AB	MUTUAL PHARM	10MG	N73535 001		
> ADD >			MAR 12, 1993		
> ADD > AB		20MG	N73536 001		
> ADD >			MAR 12, 1993		
AB	ROXANE	10MG	N73651 001		
			FEB 26, 1993		
AB		20MG	N73651 002		
			FEB 26, 1993		

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE

/AB/	/ADRIA/	/8MEQ/	/N73398/001/ /JAN/28,/1992/
/AB/		/10 MEQ/	/N72427/001/ /MAR/28,/1990/
AB	SAVAGE	8MEQ	N73398 001 JAN 28, 1992
AB		10 MEQ	N72427 001 MAR 28, 1990

TABLET, EXTENDED RELEASE; ORAL

K+8

AB	ALRA	8MEQ	N70998 001 JAN 25, 1993

KAON CL

> DLT >	/ADRIA/	/6.7MEQ/	/N17046/001/
> ADD >	SAVAGE	6.7MEQ	N17046 001

KAON CL-10

> DLT > /BC/	/ADRIA/	/10MEQ/	/N17046/002/
> ADD > BC	SAVAGE	10MEQ	N17046 002

PRAVASTATIN SODIUM

TABLET; ORAL

PRAVACHOL

> DLT >	/#//BRISTOL/MYERS/SQUIBB/10MG/	/N19898/003/ /OCT/31,/1991/
> DLT >		
> ADD >	+ BRISTOL MYERS SQUIBB 40MG	N19898 004 MAR 22, 1993
> ADD >	20MG	N19898 003 OCT 31, 1991
> ADD >		

PRAZEPAM

/TABLET;ORAL/
/CENTRAX/
/+//PARKE/DAVIS/ /10MG/ /N17415/001/
@ PARKE DAVIS 10MG N17415 001

PREDNISONE

TABLET; ORAL
DELTASONE
AB UPJOHN 2.5MG N09986 005
/BX/ /2.5MG/ /N09986/005/

PREDNISONE
/AB/ /HEATHER/ /10MG/ /N84341/001/
/AB/ /20MG/ /N85543/001/
/AB/ /50MG/ /N86946/001/
@ HEATHER 10MG N84341 001
@ 20MG N85543 001
@ 50MG N86946 001

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINAMIDE HCL
/AP/ /LYPHOMED/ /100MG/ML/ /N89415/001/
NOV 17, 1986
/AP/ /500MG/ML/ /N89416/001/
NOV 17, 1986
@ LYPHOMED 100MG/ML N89415 001
NOV 17, 1986
@ 500MG/ML N89416 001
NOV 17, 1986

PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL
PROMETHACON
> DLT > /BR/ /ALCON/ /25MG/ /N84901/001/
> DLT > /BR/ /50MG/ /N84902/001/
> ADD > BR POLYMEDICA 25MG N84901 001
> ADD > BR 50MG N84902 001

TABLET; ORAL
PROMETHAZINE HCL
/BP/ /BOLAR/ /25MG/ /N83204/001/
@ BOLAR 25MG N83204 001
/BP/ /ZENITH/ /50MG/ /N83613/001/
@ ZENITH 50MG N83613 001

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION
MESTINON
> ADD > AP ROCHE 5MG/ML N09830 001
> DLT > /AP/ /ICN/ /5MG/ML/ /N09830/001/

SYRUP; ORAL
MESTINON
> ADD > ROCHE 60MG/5ML N15193 001
> DLT > /ICN/ /60MG/5ML/ /N15193/001/

TABLET; ORAL
MESTINON
> ADD > + ROCHE 60MG N09829 002
> DLT > /+//ICN/ /60MG/ /N09829/002/

TABLET, EXTENDED RELEASE; ORAL
MESTINON
> ADD > + ROCHE 180MG N11665 001
> DLT > /+//ICN/ /180MG/ /N11665/001/

QUAZEPAM

TABLET; ORAL
DORAL
> DLT > /+//BAKER/NORTON/ /15MG/ /N18708/001/
DEC 27, 1985
> DLT > /7.5MG/ /N18708/003/
> DLT > FEB 26, 1987
> ADD > + WALLACE 15MG N18708 001
> ADD > DEC 27, 1985
> ADD > 7.5MG N18708 003
> ADD > FEB 26, 1987

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL
> DLT > /DURAQUIN/
> DLT > /PARKE/DAVIS/ /330MG/ /N17917/001/
> ADD > @ WARNER CHILCOTT 330MG N17917 001

SERACTIDE ACETATE

>DLT>	/INJECTABLE;/INJECTION/				
>DLT>	/ACTHAR/GEL-SYNTHETIC/				
>DLT>	/ARMOUR/	/40/UNITS/ML/	/N17861/001/		
>DLT>		/80/UNITS/ML/	/N17861/002/		
>ADD>	ə ARMOUR	40 UNITS/ML	N17861 001		
>ADD>	ə	80 UNITS/ML	N17861 002		

SODIUM CHLORIDE

INJECTABLE; INJECTION

BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	FUJISAWA	9MG/ML	N88911 001 FEB 07, 1985	
/AP/	/LYPHOMED/	/9MG/ML/	/N88911/001/ /FEB/07,/1985/	

SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE

>DLT> /AB/	/CHELSEA/	/25MG/	/N87078/001/	
>ADD> B*	CHELSEA	25MG	N87078 001	

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

/AB/	/HEATHER/	/500MG/	/N80189/001/	
	ə HEATHER	500MG	N80189 001	

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

	/TECHNETIUM/TC/99M/MAA/			
/BS/	/MEDI/PHYSICS/	/N/A/	/N17773/001/	
	ə MEDI PHYSICS	N/A	N17773 001	

THEOPHYLLINE SODIUM GLYCINATE

>DLT>	/ELIXIR;/ORAL/			
>DLT>	/SYNOPHYLATE/			
>DLT>	/CENTRAL/PHARMS/	/EQ/165MG/BASE/15ML/	/N06333/008/	
>ADD>	ə CENTRAL PHARMS	EQ 165MG BASE/15ML	N06333 008	

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

/AB/	/ZENITH/	/100MG/	/N88273/001/ /OCT/03,/1983/	
	ə ZENITH	100MG	N88273 001 OCT 03, 1983	

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

TICLID

>ADD>	+ SYNTEX	250MG	N19979 002 OCT 31, 1991	
>ADD>	ə	125MG	N19979 001 MAR 24, 1993	
>DLT>		/250MG/	/N19979/002/ /OCT/31,/1991/	

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL

>ADD> AB	MUTUAL PHARM	50MG	N73136 001 MAR 24, 1993	
>ADD> AB		100MG	N73137 001 MAR 24, 1993	

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE

/AT/	/PHARMADERM/	/0.025%/	/N87990/001/ /JUL/07,/1983/	
/AT/		/0.1%/	/N87991/001/ /JUL/07,/1983/	
/AT/		/0.5%/	/N87992/001/ /JUL/07,/1983/	
	ə PHARMADERM	0.025%	N87990 001 JUL 07, 1983	
	ə	0.1%	N87991 001 JUL 07, 1983	
	ə	0.5%	N87992 001 JUL 07, 1983	

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE

/AT/	/PHARMADERM/	/0.025%/	/N88692/001/ /AUG/02,/1984/
/AT/		/0.1%/	/N88690/001/ /AUG/02,/1984/
	∂ PHARMADERM	0.025%	N88692 001 AUG 02, 1984
	∂	0.1%	N88690 001 AUG 02, 1984

TRIFLUPROMAZINE

/SUSPENSION;/ORAL/
/VESPRIN/
/SQUIBB/ /EQ/50MG/HCL/5ML/ /N11491/004/
∂ APOTHECON EQ 50MG HCL/5ML N11491 004

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
VERAPAMIL HCL

AP	MARSAM	2.5MG/ML	N72233 001 FEB 26, 1993

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

FUJISAWA	1MG/ML	N89515 001 APR 29, 1987
/LYPHOMED/	/1MG/ML/	/N89515/001/ /APR/29,/1987/

VITAMIN A PALMITATE

CAPSULE; ORAL
AFAXIN
∂ STERLING EQ 50,000 UNITS BASE N83187 001
VITAMIN A

/AA/	/ZENITH/	/EQ 50,000 UNITS BASE/	/N83035/001/
/AA/		/EQ 50,000 UNITS BASE/	/N83190/001/
	∂ ZENITH	EQ 50,000 UNITS BASE	N83035 001
	∂	EQ 50,000 UNITS BASE	N83190 001

XENON, XE-133

GAS; INHALATION
XENON XE 133

AA	MEDI PHYSICS	10MCI/VIAL	N17687 002
AA		20MCI/VIAL	N17687 003

XYLOSE

POWDER; ORAL
XYLO-PFAN

/AA/	/ADRIA/	/25GM/BOT/	/N17605/001/
AA	SAVAGE	25GM/BOT	N17605 001

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

ISOCLOR			
CIBA	8MG;120MG	N18747 001	
		MAR 06, 1986	
/FISONS/	/8MG;120MG/	/N18747/001/	
		/MAR/06,/1986/	

IBUPROFEN

TABLET; ORAL

IBUPROFEN			
/LUCHEM/	/200MG/	/N72901/001/	
		/DEC/19,/1991/	
	/200MG/	/N72903/001/	
		/DEC/19,/1991/	
IBUPROFEN			
NORTON HN	200MG	N71144 001	
		JAN 20, 1987	
	200MG	N72901 001	
		DEC 19, 1991	
	200MG	N72903 001	
		DEC 19, 1991	
> DLT > /IBUPROFEN/			
> DLT > /OHM/	/200MG/	/N71214/001/	
> DLT >		/DEC/01,/1986/	
IBUPROFEN			
/ZENITH/	/200MG/	/N71154/001/	
		/OCT/27,/1987/	
@ ZENITH	200MG	N71154 001	
		OCT 27, 1987	
> ADD > IBUPROHM			
> ADD > OHM	200MG	N71214 001	
> ADD >		DEC 01, 1986	
/NEUVIL/			
/LUCHEM/	/200MG/	/N71144/001/	
		/JAN/20,/1987/	

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

> DLT > /CAPSULE;/ORAL/
> DLT > /ACTIFED/
> DLT > /BURROUGHS/WELLCOME/ /60MG;2.5MG/ /N19208/001/
> DLT > /JAN/15,/1985/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

> DLT > /SYRUP;/ORAL/			
> DLT > /ACTIFED/			
> DLT > /BURROUGHS/WELLCOME/	/30MG/5ML;1.25MG/5ML/	/N11935/003/	
> DLT >		/NOV/26,/1982/	
> DLT > /TRIOFED/			
> DLT > /BARRE/	/30MG/5ML;1.25MG/5ML/	/N88115/001/	
> DLT >		/MAR/04,/1983/	
> DLT > /TRIPOSED/			
> DLT > /HALSEY/	/30MG/5ML;1.25MG/5ML/	/N88213/002/	
> DLT >		/MAR/30,/1984/	
> DLT > /TABLET;/ORAL/			
> DLT > /ACTIFED/			
> DLT > /BURROUGHS/WELLCOME/	/60MG;2.5MG/	/N11936/002/	
> DLT >		/NOV/26,/1982/	
> DLT > /TRI-SUDO/			
> DLT > /MD/PHARM/	/60MG;2.5MG/	/N85024/002/	
> DLT >		/JAN/10,/1984/	
> DLT > /TRIPODRINE/			
> DLT > /DANBURY/	/60MG;2.5MG/	/N88112/001/	
> DLT >		/JAN/20,/1983/	
> DLT > /TRIPOSED/			
> DLT > /HALSEY/	/60MG;2.5MG/	/N88192/002/	
> DLT >		/MAY/01,/1984/	
> DLT > /TRIPROLIDINE/HCL/AND/PSEUDOEPHEDRINE/HCL/			
> DLT > /CHELSEA/	/60MG;2.5MG/	/N88118/002/	
> DLT >		/JAN/26,/1984/	

INDIUM^{111} CHLORIDE

SOLUTION; INJECTION

INDICLOR		
AMERSHAM	N/A	N19862
		DEC 29, 1992

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January thru March 1993]

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
ATOVAQUONE TN= MEPRON	TREATMENT AND SUPPRESSION OF TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / /
ATOVAQUONE TN= MEPRON	PRIMARY PROPHYLAXIS OF HIV-INFECTED PERSONS AT HIGH RISK FOR DEVELOPING TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/83 MA / /
COLFOSCERIL PALMITATE, CETYL ALCOHOL, TYLOXAPOL TN= EXOSURF	TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 01/11/93 MA / /
CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR GENE TN=	TREATMENT OF CYSTIC FIBROSIS.	GENETIC THERAPY, INC. 19 FIRSTFIELD ROAD GAITHERSBURG MD 20878 DD 01/08/93 MA / /
HUMANIZED ANTI-TAC TN=	PREVENTION OF ACUTE RENAL ALLOGRAFT REJECTION.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND STREET NUTLEY NJ 07110 DD 03/05/93 MA / /
HUMANIZED ANTI-TAC TN=	PREVENTION OF ACUTE GRAFT-VS-HOST DISEASE FOLLOWING BONE MARROW TRANSPLANTATION.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND STREET NUTLEY NJ 07110 DD 03/05/93 MA / /
IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TN= GAMIMUNE N	INFECTION PROPHYLAXIS IN PEDIATRIC PATIENTS AFFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS.	MILES, INC. 4TH & PARKER STREETS BERKELEY CA 94710 DD 02/18/93 MA / /
INTERFERON BETA, RECOMBINANT HUMAN TN=	TREATMENT OF PRIMARY BRAIN TUMORS.	BIOGEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02142 DD 01/13/93 MA / /
MODAFINIL TN=	TREATMENT OF EXCESSIVE DAYTIME SLEEPINESS IN NARCOLEPSY.	CEPHALON, INC. 145 BRANDYWINE PARKWAY WEST CHESTER PA 19380-4245 DD 03/15/93 MA / /
MONOCLONAL ANTIBODY FOR IMMUNIZATION AGAINST LUPUS NEPHRITIS TN=	TREATMENT OF LUPUS NEPHRITIS.	MEDCLONE, INC. 2435 MILITARY AVENUE LOS ANGELES CA 90064 DD 01/07/93 MA / /
RILUZOLE TN=	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	RHONE-POULENC RORER PHARM. 500 ARCOLA ROAD, PO BOX 1200 COLLEGEVILLE PA 19426-0107 DD 03/16/93 MA / /
SOMATROPIN TN= BIOTROPIN	TREATMENT OF CACHEXIA ASSOCIATED WITH AIDS.	BIO-TECHNOLOGY GENERAL CORPORATION 1250 BROADWAY, 20th FLOOR NEW YORK NY 10001 DD 02/12/93 MA / /
THALIDOMIDE TN=	TREATMENT OF THE CLINICAL MANIFESTATIONS OF MYCOBACTERIAL INFECTION CAUSED BY MYCOBACTERIUM TUBERCULOSIS AND NON-TUBERCULOUS MYCOBACTERIA.	CELGENE CORPORATION 7 POWDER HORN DRIVE WARREN NJ 07059 DD 01/12/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD= Date Designated MA= Marketing Approval
TRETINOIN TN= TRETINOIN LF, IV	TREATMENT OF ACUTE AND CHRONIC LEUKEMIA.	ARGUS PHARMACEUTICALS, INC. 3400 RESEARCH FOREST DRIVE THE WOODLANDS TX 77381 DD 01/14/93 MA / /
TUMOR NECROSIS FACTOR-BINDING PROTEIN 1 TN=	TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 COUNTS LESS THAN 200 CELLS PER MM3.	SERONO LABORATORIES, INC. 100 LONGWATER CIRCLE NORWELL MA 02061 DD 01/06/93 MA / /
TUMOR NECROSIS FACTOR-BINDING PROTEIN II TN=	TREATMENT OF SYMPTOMATIC PATIENTS WITH THE ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM3.	SERONO LABORATORIES, INC. 100 LONGWATER CIRCLE NORWELL MA 02061 DD 01/06/93 MA / /

Orphan Drug Approvals

ANTIHEMOPHILIC FACTOR (RECOMBINANT) TN= KOGENATE	PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.	MILES, INC. 4TH & PARKER STREETS BERKELEY CA 94701 DD 09/25/89 MA 02/25/93
[redacted]BINE [redacted]LEUSTATIN INJECTION	TREATMENT OF HAIRY CELL LEUKEMIA.	R.W.JOHNSON RESEARCH INSTITUTE ROUTE 202, PO BOX 300 RARITAN NJ 08869-0602 DD 11/15/90 MA 02/26/93

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

NO MARCH 1993 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM) DATE REVISED DATE

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTING. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE (HFD-650, MPN-2 ROOM 279) 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

TRIAZOLAM (TABLET) DEC 24, 1992

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.					
REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.					
AMINOSALICYLIC ACID GRANULES, ENTERIC-COATED; ORAL	4GM/PACKET	92 P-0356/ CP1	JACOBUS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 03, 1993
CHLORPROMAZINE HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML	92 P-0284/ CP1	UDL	NEW STRENGTH	APPROVED JAN 07, 1993
DOBUTAMINE HYDROCHLORIDE INJECTABLE; INJECTION	EQ 12.5MG BASE/ML (40ML/VIAL)	92 P-0365/ CP1	LYPHOMED	NEW STRENGTH	APPROVED FEB 11, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (12.5MG/VIAL)	92 P-0355/ CP1	LEDERLE	NEW STRENGTH	APPROVED JAN 07, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/CONTAINER)	91 P-0460/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 11, 1993
LACTULOSE CRYSTAL; ORAL	10GM/PACKET	92 P-0370/ CP1	BENNETT AND COMPANY	NEW DOSAGE FORM	APPROVED JAN 07, 1993
METHYLPHENIDATE HYDROCHLORIDE; TABLET, EXTENDED RELEASE; ORAL	10MG	92 P-0400/ CP1	MD PHARM	NEW STRENGTH	APPROVED MAR 22, 1993

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW INDICATION

I-87 RENAL IMAGING AGENT FOR USE IN CHILDREN
I-88 MANAGEMENT OF ENDOMETRIOSIS
I-89 EPIDURAL USE IN LABOR AND DELIVERY AS AN ANALGESIC ADJUNCT TO BUPIVACAINE

REFERENCES
PATENT USE CODE

U-74 METHOD OF PROVIDING HYPNOTIC EFFECT
U-75 RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS
U-76 USE TO IMAGE A SUBJECT WITH A MAGNETIC RESONANCE IMAGING SYSTEM

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19604 001	ALBUTEROL SULFATE; VOLMAX	4851229	JUN 14, 2005			
			4777049	OCT 11, 2005			
			4751071	JUN 14, 2005			
	19604 002	ALBUTEROL SULFATE; VOLMAX	4851229	JUN 14, 2005			
			4777049	OCT 11, 2005			
			4751071	JUN 14, 2005		NS	DEC 23, 1995
	20045 001	AVOBENZONE; SHADE UVAGUARD	4522807	JUN 11, 2002		NC	DEC 07, 1995
			4387089	JUN 07, 2002			
	19807 001	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4252984	AUG 30, 1999			
	19807 002	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4252984	AUG 30, 1999			
>ADD>	20186 001	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
>ADD>						NC	FEB 26, 1996
>ADD>	20186 002	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
>ADD>						NC	FEB 26, 1996
>ADD>	20186 003	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
>ADD>						NC	FEB 26, 1996
	20229 001	CLADRIBINE; LEUSTATIN				NCE	FEB 26, 1998
>ADD>						ODE	FEB 26, 2000
	18651 001	DRONABINOL; MARINOL				ODE	DEC 22, 1999
	18651 002	DRONABINOL; MARINOL				ODE	DEC 22, 1999
	18651 003	DRONABINOL; MARINOL				ODE	DEC 22, 1999
	19616 004	ENOXACIN; PENETREX	4359578	NOV 16, 2001		NCE	DEC 31, 1996
	19616 005	ENOXACIN; PENETREX	4359578	NOV 16,.2001		NCE	DEC 31, 1996
>ADD>	20164 001	ENOXAPARIN SODIUM; LOVENOX				NCE	MAR 29, 1998
	20073 001	FLUMAZENIL; MAZICON	4316839	MAR 03, 2003		NCE	DEC 20, 1996
	20068 001	FOSCARNET SODIUM; FOSCAVIR	4215113	JUN 06, 2000	U-64	NCE	SEP 27, 1996
	20123 001	GADODIAMIDE; OMNISCAN	4687659	AUG 18, 2004	U-76	NCE	JAN 08, 1998
	19726 001	GOSERELIN ACETATE; ZOLADEX				I-88	FEB 02, 1996
	19891 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
	19892 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
	19084 001	KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999		I-30	JAN 27, 1996
	19700 001	KETOROLAC TROMETHAMINE; ACULAR	5110493	MAY 05, 2009	U-75	NCE	NOV 30, 1994
			4454151	JUN 12, 2001	U-75	NDF	NOV 09, 1995
			4089969	MAY 16, 1997	U-75		
	18948 001	LEVOCARNITINE; CARNITOR				I-86	DEC 16, 1995
	18948 002	LEVOCARNITINE; CARNITOR				I-86	DEC 16, 1995
	20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	4528287	MAY 05, 2005	U-36	NCE	FEB 21, 1997
	20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	JAN 22, 2006		NCE	JAN 22, 1997
	20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	JAN 22, 2006		NCE	JAN 22, 1997

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2002		NCE	DEC 24, 1996
	19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2002		NCE	DEC 24, 1996
	20109 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
	20150 001	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
	20150 002	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
	20150 003	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
	20066 001	NICOTINE POLACRILEX; NICORETTE DS				NCE	JAN 13, 1994
	20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004		NCE	JAN 04, 1996
	20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004		NCE	JAN 04, 1996
	20036 001	PAMIDRONATE DISODIUM; AREDIA	3962432	FEB 01, 1997	U-53		
	19568 001	PREDNICARBATE; DERMATOP	4242334	DEC 30, 1999	U-50	NE	SEP 23, 1994
	50689 001	RIFABUTIN; MYCOBUTIN				ODE	DEC 23, 1999
	19839 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
	19839 002	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
	19839 003	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
	19839 004	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
	19766 001	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
	19766 002	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
	19766 003	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
	19766 004	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
>ADD>	19050 001	SUFENTANIL CITRATE; SUFENTA				NR	MAR 19, 1996
>ADD>						I-89	MAR 19, 1996
	20080 001	SUMATRIPTAN SUCCINATE; IMITREX	4816470	MAR 28, 2006	U-72		
	19882 001	TECHNETIUM TC-99M MERTIATIDE KIT; TECHNESCAN MAG3				I-87	NOV 27, 1995
	20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	JAN 30, 2006	U-36	NCE	JAN 30, 1997
	20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	JAN 30, 2006	U-36	NCE	JAN 30, 1997
	18163 003	TEMAZEPAM; RESTORIL	5030632	JUL 09, 2008	U-70	NS	OCT 25, 1994
	19979 002	TICLOPIDINE HYDROCHLORIDE; TICLID	4591592	NOV 01, 2005			
			4051141	SEP 27, 1996		NCE	OCT 31, 1996
	18776 003	VECURONIUM BROMIDE; NORCURON	4297351	OCT 27, 1998			
			4237126	DEC 02, 1997		NCE	APR 30, 1994
	19908 001	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 10, 2000	U-74	NCE	DEC 16, 1997
	19908 002	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 10, 2000	U-74	NCE	DEC 16, 1997

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19862 001	INDIUM 111 CHLORIDE; INDICLOR				NCE	DEC 29, 1997

*U.S. Government Printing Office: 1993 — 342-345/60010

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