APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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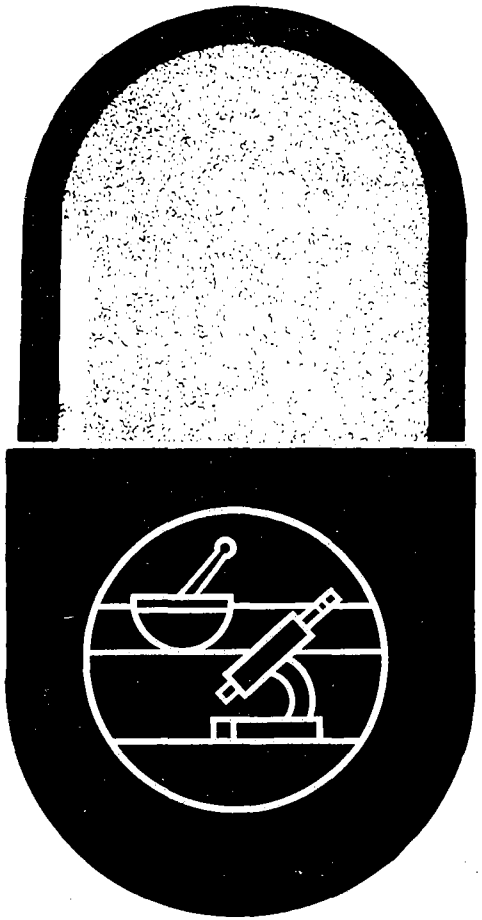
CUMULATIVE SUPPLEMENT 16

AUG'85-DEC'86



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

6TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUGS AND BIOLOGICS

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

6TH EDITION

CUMULATIVE SUPPLEMENT

DECEMBER 1986

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APPROVED DRUG PRODUCTS

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6th EDITION

CUMULATIVE SUPPLEMENT

DECEMBER 1986

A. INTRODUCTION

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, 6th Edition (the List). The List is comprised of three drug product lists: The Prescription Drug Product list, the OTC Drug Product list, and the Drug Products Approved Under Section 505 of the Act by the Division of Blood and Blood Products list. 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.

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.

Information in the Cumulative Supplement follows the format of the drug product lists. 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.)

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the drug product lists for the revision. [Strength(s) which already exist in the publication will not be repeated for context.] A page number in parentheses, located to the right of the ingredient(s), refers to the related page in the drug product lists. The effective (marketing) date (the date a product may be marketed), when appropriate, will appear to the left of the approval date.

Additions to the drug product lists and the Appendices are indicated by new information in the Cumulative Supplement. Additions new to the current Cumulative Supplement are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is dropped in subsequent Cumulative Supplements for that item.

A newly approved product is identified by the lozenge (¤) to the right of its strength. This identifier remains throughout all Cumulative Supplements for this edition.

Deletions from the drug product lists and the Appendices are indicated by overstruck print in the Cumulative Supplement. Deletions new to the current Cumulative Supplement are indicated by the symbol >DLT> (DELETE) to the left of the line containing the overstruck print. The symbol is dropped in subsequent Cumulative Supplements for that item.

Products discontinued from marketing will be flagged in this Cumulative Supplement with the "◕" symbol to designate their non-marketed status until such time that the Agency is notified that they are being marketed.

The Appendices of the Cumulative Supplement provide, among other things, updated information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984."

2. APPLICANT (NAME) CHANGES

Because 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, the cumulation of these transfers and name changes will be identified in this Special Notes 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. The current list of applicant holder changes follows.

APPLICANT (NAME) CHANGES

Former Applicant (Name)	New Applicant (Name)	New Abbreviated Name
VITARINE/PHOENIX	VITARINE PHARMACEUTICALS, INC	VITARINE PHARMS
DRUMMER/PHOENIX	VITARINE PHARMACEUTICALS, INC	VITARINE PHARMS
INVENEX LABS/LIFE	LYPHOMED, INC	LYPHOMED
ONEAL JONES&FELDMAN	FOREST PHARMACEUTICALS, INC SUBSIDIARY OF FOREST LABORATORIES, INC	FOREST PHARMS/FOREST
AM MCGAW/AM HOSP	KENDALL MCGAW LABORATORIES, INC	KENDALL MCGAW LABS

(continued)

APPLICANT (NAME) CHANGES

(continued)

Former Applicant (Name)	New Applicant (Name)	New Abbreviated Name
IVES LABS/AMHO	WYETH LABORATORIES, INC DIVISION OF AMERICAN HOME PRODUCTS CORP	WYETH LABS/AMHO
REID PROVIDENT LABS AND ROWELL LABORATORIES	REID-ROWELL	REID-ROWELL
BAY LABORATORIES	MY-K LABORATORIES, INC	MY-K LABS
AMERICAN CRITICAL CARE DIV AMERICAN HOSP SUPPLY CORP	AM CRITICAL CARE/AHS	DUPONT CRIT CRE

3. PREDNISONE BIOEQUIVALENCE

The Agency has determined that in vitro data are sufficient to demonstrate bioequivalence of prednisone products. This decision is based on past bioavailability studies on a variety of prednisone products sponsored under FDA contract which established an in vitro and in vivo correlation with a variety of in vitro apparatus and media. The studies demonstrated that the dissolution rate using apparatus such as the spin filter, USP basket, and paddle correlated with the rate of drug absorption. The initial paddle used in the above studies was a tilting blade paddle. When the USP adopted a fixed blade paddle method, it raised the issue of whether the same correlation existed for the tilting blade paddle. Following the October 15, 1977, effective date of the new USP prednisone table dissolution specification, the Agency initiated an extensive voluntary dissolution certification program for all marketed prednisone tablet products. This program continued until each firm demonstrated that every prednisone product could consistently meet the new USP standard. Firms failing to meet the new standard were required to remove their product from the market or reformulate to an acceptable product.

As a result of this program, when marketed prednisone table products were resurveyed in 1980, all met the USP standard.

A selected sample of the products in an Agency bioavailability study conducted in 1982 on marketed prednisone tablets revealed no statistically significant differences in the key bioavailability parameters (AUC, Cmax, Tmax) for prednisone tablets.

Therefore, FDA will change the therapeutic equivalence code from BX to AB on any approved prednisone tablets if the application is supplemented with an acceptable comparative in vitro dissolution study. (See Appendix 3 of this Supplement for available guidance from the Division of Bioequivalence.)

4. OTC DRUG PRODUCTS

The following drug products identified in the "OTC Drug Product List" of this publication as requiring approved applications may be marketed on the firm's own responsibility without an application under the Agency's existing OTC drug marketing policies so long as applicable proposed or tentative final monographs are followed (see 21 CFR 330.13).

Dexbrompheniramine Maleate	2mg
Pseudoephedrine Sulfate	60mg
Tablet; Oral	
Pseudoephedrine HCl	60mg
Triprolidine HCl	2.5mg
Tablet or Capsule; Oral	
Pseudoephedrine HCl	30mg/5ml
Triprolidine HCl	1.25mg/5ml
Syrup; Oral	
Triprolidine HCl	1.25mg/5ml
Syrup; Oral	
Triprolidine HCl	2.5mg
Tablet; Oral	

5. 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
neomycin sulfate with either: dexamethasone sodium phosphate, fluocinolone acetonide, flurandrenolide, hydrocortisone, or methylprednisolone acetate [topical anti-infectives for dermatologic use]	MAR 26, 1984 (49 FR 11888)
nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (ointment;topical)	SEP 3, 1986 (51 FR 31371)
nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

6. INJECTABLE PRODUCT PACKAGE SIZE DESIGNATION

When a new drug product (usually injectable) is approved for the same concentration but a different package size than the listed drug, and it has received a period of exclusivity by the Agency, the product will appear as single source (no therapeutic equivalence code displayed) and the potency will reflect the unique package size. Once the period of exclusivity has ended, the product will then conform to the standard ADP format of reflecting "collapsed" package sizes. The current standard is to display package sizes of all small volume parenterals within an NDA as a per ml concentration and large volume parenterals as per 100ml.

7. 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. Thus, 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 those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods.

The counts appear in two sections. Section A. provides baseline and quarterly data. The baseline column refers to the products in the List. For each three-month period following July '85, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count. Section B. refers to products in the Cumulative Supplements and provides monthly activity with a cumulative count for the current quarter.

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 part of a combination.

USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved and remarketed drug products which are added to the List; (2) products that are being removed from the List as the result of withdrawal of approval and changes from prescription to over-the-counter status; and, (3) trends in approval of products as either multisource or single source during each month within the quarter. The report does not reflect category changes from multisource to single source and vice versa. However, the net gain that results from all additions, deletions and category changes is reflected in the quarterly counts for multisource and single source products.

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

CATEGORIES COUNTED	JULY '85 (BASELINE)	JUL '86	OCT '86
DRUG PRODUCTS LISTED	8048	8860	9066
SINGLE SOURCE	2096 (26.0%)	2137 (24.1%)	2128 (23.5%)
MULTISOURCE(1)	5952 (74.0%)	6723 (75.9%)	6938 (76.5%)
THERAPEUTICALLY EQUIVALENT	4864 (60.5%)	5619 (63.4%)	5850 (64.5%)
NOT THERAPEUTICALLY EQUIVALENT	1054 (13.1%)	1062 (12.1%)	1039 (11.5%)
EXCEPTIONS(2)	34 (0.4%)	42 (0.4%)	49 (0.5%)
NEW MOLECULAR ENTITIES APPROVED	-	27	8
NUMBER OF APPLICANTS	306	327	330

B. ACTIVITY FOR SUPPLEMENT NUMBER 16

	NOV '86	DEC '86	CUMULATIVE
DRUG PRODUCTS ADDED:	81	108	189
NEWLY APPROVED	80	107	187
DESI EFFECTIVE	0	1	1
REMARKETED	1	0	1
DRUG PRODUCTS REMOVED:	0	0	0
WITHDRAWN APPROVAL	0	0	0
RX TO OTC SWITCH	0	0	0
NET GAIN IN DRUG PRODUCTS	81	108	189
SINGLE SOURCE PRODUCTS APPROVED	7	36	43
MULTISOURCE DRUG PRODUCTS APPROVED	74	72	146
NEW MOLECULAR ENTITIES APPROVED:	0	10	10
AS THE ENTITY	0	3	3
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	7	7

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (i.e., AVAILABLE FROM MORE THAN ONE APPLICANT)

(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE I-8 OF THE LIST)

B. DRUG PRODUCT LISTS

1. Prescription Drug Product List

2. OTC Drug Product List

3. Drug Products Approved Under Section 505 of the Act by the Division of Blood and Blood Products List

ACETAMINOPHEN (PAGE 3-1)

INJECTABLE; INJECTION
INJECTAPAP
MCNEIL PHARM 100MG/ML¤ N17785 001
MAR 07, 1986

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

CAPSULE; ORAL
BANCAP
FOREST PHARM/FOREST 325MG;50MG¤ N88889 001
JAN 16, 1986

TABLET; ORAL
SEDAPAP-10
MAYRAND 650MG;50MG¤ N88944 001
OCT 17, 1985

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL
ACETAMINOPHEN, BUTALBITAL, AND CAFFEINE
AB MIKART 325MG;50MG;40MG¤ N89007 001
MAR 17, 1986

AHOQUAN
AB MALLARD 325MG;50MG;40MG¤ N87628 001
OCT 01, 1986

MEDIGESIC PLUS
AB US CHEM MKTG GROUP 325MG;50MG;40MG¤ N89115 001
JAN 14, 1986

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE (PAGE 3-1)

CAPSULE; ORAL
COMPAL
AA REID-ROWELL 356.4MG;30MG;16MG¤ N88584 001
MAR 04, 1986

SYNALGOS-DC-A
AA WYETH LABS/AMHO 356.4MG;30MG;16MG¤ N89166 001
MAY 14, 1986

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL
ACETAMINOPHEN AND CODEINE
AA VITARINE 300MG;15MG N87433 001
AA 300MG;30MG N85917 001
AA 300MG;60MG N87423 001

ACETAMINOPHEN AND CODEINE PHOSPHATE
AA MIKART 650MG;30MG¤ N89231 001
MAR 03, 1986

ACETAMINOPHEN AND CODEINE PHOSPHATE #2
AA SUPERPHARM 300MG;15MG¤ N89183 001
OCT 18, 1985

ACETAMINOPHEN AND CODEINE PHOSPHATE #3
AA MIKART 300MG;30MG¤ N89238 001
FEB 25, 1986
AA PUREPAC/KALIPHARMA 300MG;30MG¤ N89080 001
JUL 17, 1986
AA SUPERPHARM 300MG;30MG¤ N89184 001
OCT 18, 1985
AA 300MG;30MG¤ N89253 001
MAY 19, 1986

ACETAMINOPHEN AND CODEINE PHOSPHATE #4
AA MIKART 300MG;60MG¤ N89244 001
FEB 25, 1986
AA SUPERPHARM 300MG;60MG¤ N89185 001
OCT 18, 1985
AA 300MG;60MG¤ N89254 001
MAY 19, 1986

ACETAMINOPHEN W/ CODEINE
/AA/ /VITARINE/ /300MG;30MG/ /N85917.001/
ACETAMINOPHEN W/ CODEINE #2
/AA/ /VITARINE/ /300MG;15MG/ /N87433.001/
ACETAMINOPHEN W/ CODEINE #4
/AA/ /VITARINE/ /300MG;60MG/ /N87423.001/
PHENAPHEN-650 W /CODEINE
AA AH ROBINS 650MG;30MG N85856 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL
ACETAMINOPHEN AND HYDROCODONE BITARTRATE
AA DM GRAHAM LABS 500MG;5MG¤ N89006 001
AUG 09, 1985

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL

BANCAP HC

AA	FOREST PHARM/FOREST	500MG;5MG	N87961 001	MAR 17, 1983
/AA/	/ONEAL JONES&FELDMAN//500MG;5MG/		/N87961 001/	/MAR 17, 1983/

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	MIKART	500MG;5MG¤	N89008 001	FEB 21, 1986

TABLET; ORAL

DURADYNE DHC

AA	FOREST PHARM/FOREST	500MG;5MG	N87809 001	MAR 17, 1983

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	MIKART	500MG;5MG¤	N89271 001	JUL 16, 1986

NORCET

AA	HOLLOWAY PHARMS	500MG;5MG¤	N88871 001	MAY 15, 1986

TYCODONE

AA	MCNEIL PHARM	500MG;5MG¤	N89385 001	AUG 27, 1986

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; (PAGE 3-3)

> ADD > SOLUTION; ORAL

> ADD > **ROXICET**

> ADD >	ROXANE LABORATORIES	325MG/5ML;5MG/5ML¤	N89351 001	DEC 03, 1986

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL

/**PROVOCET 100**/

PROPACET 100

AB	LEMMON	650MG;100MG	N70107 001	JUN 12, 1985

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

AB	BARR LABORATORIES	650MG;100MG¤	N70615 001	MAR 21, 1986
AB		650MG;100MG¤	N70771 001	MAR 21, 1986
AB		650MG;100MG¤	N70775 001	MAR 21, 1986

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

> ADD > AB	BOLAR PHARMACEUTICAL	325MG;50MG¤	N70398 001	DEC 18, 1986
> ADD > AB		650MG;100MG¤	N70399 001	DEC 18, 1986
> ADD > AB	CHELSEA LABORATORIES	325MG;50MG¤	N71336 001	DEC 11, 1986
> ADD > AB		650MG;100MG¤	N71337 001	DEC 11, 1986
AB	CORD LABORATORIES	650MG;100MG¤	N70443 001	JAN 23, 1986
AB	LEMMON	650MG;100MG¤	N70732 001	JAN 03, 1986
AB	ZENITH LABORATORIES	650MG;100MG¤	N70146 001	AUG 02, 1985

ACETAZOLAMIDE (PAGE 3-4)

TABLET; ORAL

ACETAZOLAMIDE

AB	DANBURY PHARMACAL	250MG¤	N88882 001	OCT 22, 1985

ACETIC ACID, GLACIAL (PAGE 3-4)

SOLUTION/DROPS; OTIC

BOROFAIR

AT	PHARMAFAIR	2%¤	N88606 001	AUG 21, 1985

ACETOHEXAMIDE (PAGE 3-4)

TABLET; ORAL

ACETOHEXAMIDE

AB	COLMED LABORATORIES	250MG¤	N70753 001	NOV 03, 1986
AB		500MG¤	N70754 001	NOV 03, 1986

DYMELOR

AB	ELI LILLY INDSTRS/PR	250MG	N13378 002	
AB		500MG	N13378 001	

ACETYLCYSTEINE (PAGE 3-5)

SOLUTION; INHALATION

MUCOMYST

AN	MEAD JOHNSON/B-M	10%	N13601 002	
AN		20%	N13601 001	

ACETYLCYSTEINE (PAGE 3-5)

SOLUTION; INHALATION

	MUCOSOL-10			
AN	DEY LABORATORIES	10%		N70575 001
				OCT 14, 1986
	MUCOSOL-20			
AN	DEY LABORATORIES	20%		N70576 001
				OCT 14, 1986

ACYCLOVIR (PAGE 3-5)

CAPSULE; ORAL

	ZOVIRAX			
	BURROUGHS WELLCOME	200MG		N18828 001
				/JAN 28, 1985/
				JAN 25, 1985

ALBUTEROL SULFATE (PAGE 3-6)

TABLET; ORAL

	PROVENTIL			
AB	SCHERING	EQ 2MG BASE		N17853 001
				MAY 07, 1982
AB		EQ 4MG BASE		N17853 002
				MAY 07, 1982
	VENTOLIN			
AB	GLAXO	EQ 2MG BASE		N19112 001
				JUL 10, 1986
AB		EQ 4MG BASE		N19112 002
				JUL 10, 1986

> ADD > ALFENTANIL HYDROCHLORIDE (PAGE 3-6)

> ADD > INJECTABLE; INJECTION

> ADD >	ALFENTA			
> ADD >	JANSSEN PHARMA	EQ 0.5MG BASE/ML		N19353 001
> ADD >				DEC 29, 1986

ALLOPURINOL (PAGE 3-6)

TABLET; ORAL

	ALLOPURINOL			
AB	BARR LABORATORIES	100MG		N70466 001
				/NOV 30, 1988 : DEC 24, 1985
AB		300MG		N70467 001
				/NOV 30, 1988 : DEC 24, 1985
AB	CORD LABORATORIES	100MG		N70268 001
				/NOV 30, 1988 : DEC 31, 1985
AB		300MG		N70269 001
				/NOV 30, 1988 : DEC 31, 1985

ALLOPURINOL (PAGE 3-6)

TABLET; ORAL

	ALLOPURINOL			
AB	MYLAN PHARMS	100MG		N18659 001
				OCT 24, 1986
AB		300MG		N18659 002
				OCT 24, 1986
AB	PAR PHARMACEUTICAL	100MG		N70150 001
				/NOV 30, 1988 : DEC 10, 1985
AB		300MG		N70147 001
				/NOV 30, 1988 : DEC 10, 1985
AB	PUREPAC/KALIPHARMA	100MG		N70579 001
				APR 14, 1986
AB		300MG		N70580 001
				APR 14, 1986
AB	SUPERPHARM	100MG		N70950 001
				NOV 30, 1988 : SEP 04, 1986
AB		300MG		N70951 001
				NOV 30, 1988 : SEP 04, 1986

AMANTADINE HYDROCHLORIDE (PAGE 3-7)

CAPSULE; ORAL

	AMANTADINE HCL			
AB	FORMUTEC	100MG		N70589 001
				AUG 05, 1986
AB	REID-ROWELL	100MG		N71000 001
				SEP 04, 1986
	SYMMETREL			
AB	DUPONT PHARMS/DUPONT	100MG		N16020 001
AB		100MG		N17117 001

AMILORIDE HYDROCHLORIDE (PAGE 3-7)

TABLET; ORAL

	AMILORIDE HCL			
AB	PAR PHARMACEUTICAL	5MG		N70346 001
				JAN 22, 1986
	MIDAMOR			
AB	MS&D/MERCK	5MG		N18200 001

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-7)

TABLET; ORAL

	HYDRO-RIDE			
AB	PAR PHARMACEUTICAL	5MG;50MG		N70347 001
				DEC 25, 1990 : AUG 06, 1986
	MODURETIC 5-50			
AB	MS&D/MERCK	5MG;50MG		N18201 001

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION

AMINOSYN-HBC 7% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 7%¤ N19400 001
JUL 23, 1986

AMINOSYN-PF 7%
ABBOTT LABORATORIES 7%¤ N19398 001
SEP 06, 1985

AMINOSYN-PF 10%
ABBOTT LABORATORIES 10%¤ N19492 001
OCT 17, 1986

AMINOSYN II 3.5%
ABBOTT LABORATORIES 3.5%¤ N19438 001
APR 03, 1986

AMINOSYN II 3.5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 3.5%¤ N19491 001
OCT 10, 1986

AMINOSYN II 5%
ABBOTT LABORATORIES 5%¤ N19438 002
APR 03, 1986

AMINOSYN II 7%
ABBOTT LABORATORIES 7%¤ N19438 003
APR 03, 1986

AMINOSYN II 8.5%
ABBOTT LABORATORIES 8.5%¤ N19438 004
APR 03, 1986

AMINOSYN II 10%
ABBOTT LABORATORIES 10%¤ N19438 005
APR 03, 1986

>DLT> /NEOPHAM 6.5%/
>DLT> /KABIVITRUM/ /6.5%/ /N18792 001/
>DLT> /JAN 17, 1984/
>ADD> NEOPHAM 6.4%
>ADD> KABIVITRUM 6.4% N18792 001
>ADD> JAN 17, 1984

NOVAMINE 15%
KABIVITRUM 15%¤ N17957 004
NOV 28, 1986

AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-8)

INJECTABLE; INJECTION

/PERIPHRAMINE/
PROCALAMINE
KENDALL MCGAW LABS 3%;26MG/100ML;3GM/100ML;54MG/100ML; 41MG/100ML;150MG/100ML;200MG/100ML; 120MG/100ML N18582 001
MAY 08, 1982

AMINO ACIDS; DEXTROSE (PAGE 3-8)

INJECTABLE;INJECTION

AMINOSYN II 3.5% IN DEXTROSE 5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 3.5%;5GM/100ML¤ N19506 001
NOV 07, 1986

AMINOSYN II 3.5% IN DEXTROSE 25% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 3.5%;25GM/100ML¤ N19505 001
NOV 07, 1986

AMINOSYN II 4.25% IN DEXTROSE 25% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 4.25%;25GM/100ML¤ N19504 002
NOV 07, 1986

>ADD> AMINOSYN II 5% IN DEXTROSE 25% IN PLASTIC CONTAINER
>ADD> ABBOTT LABORATORIES 5%;25GM/100ML¤ N19565 001
>ADD> DEC 17, 1986

>ADD> AMINO ACIDS; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;
>ADD> POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE (PAGE 3-8)

>ADD> INJECTABLE; INJECTION
>ADD> AMINOSYN II 3.5% W/ ELECTROLYTES IN DEXTROSE 25% IN PLASTIC
>ADD> CONTAINER
>ADD> ABBOTT LABS 3.5%;25GM/100ML;51MG/100ML;
>ADD> 22.4MG/100ML;261MG/100ML;
>ADD> 205MG/100ML N19564 002
>ADD> DEC 16, 1986
>ADD> AMINOSYN II 4.25% W/ ELECTROLYTES IN DEXTROSE 25% IN
>ADD> PLASTIC CONTAINER
>ADD> ABBOTT LABS 4.25%;25GM/100ML;51MG/100ML;
>ADD> 22.4MG/100ML;261MG/100ML;
>ADD> 205MG/100ML N19564 004
>ADD> DEC 16, 1986

>ADD> AMINO ACIDS; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE
>ADD> SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC (PAGE 3-8)

>ADD> INJECTABLE;INJECTION
>ADD> AMINOSYN II 3.5% M IN DEXTROSE 5% IN PLASTIC CONTAINER
>ADD> ABBOTT LABORATORIES 3.5%;5GM/100ML;30MG/100ML;
>ADD> 97MG/100ML;120MG/100ML;
>ADD> 49.3MG/100ML¤ N19564 001
>ADD> DEC 16, 1986
>ADD> AMINOSYN II 4.25% M IN DEXTROSE 10% IN PLASTIC CONTAINER
>ADD> ABBOTT LABORATORIES 4.25%;10GM/100ML;30MG/100ML;
>ADD> 97MG/100ML;120MG/100ML;
>ADD> 49.3MG/100ML¤ N19564 003
>ADD> DEC 16, 1986

AMINO ACIDS; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC (PAGE 3-9)

INJECTABLE; INJECTION

> DLT > /AMINOSYN II 3.5% M/
> DLT > /ABBOTT LABORATORIES//3.5%;32MG/100ML;128MG/100ML;/
> DLT > /222MG/100ML;49MG/100ML¤//N19437 007/
> DLT > /APR 03, 1986/

AMINOSYN II 3.5% M IN PLASTIC CONTAINER
ABBOTT LABORATORIES 3.5%;32MG/100ML;128MG/100ML; 222MG/100ML;49MG/100ML¤ N19493 001 OCT 16, 1986

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE (PAGE 3-9)

INJECTABLE; INJECTION

AMINOSYN II 7% W/ ELECTROLYTES
ABBOTT LABORATORIES 7%;102MG/100ML;45MG/100ML; 522MG/100ML;410MG/100ML¤ N19437 006 APR 03, 1986

AMINOSYN II 8.5% W/ ELECTROLYTES
ABBOTT LABORATORIES 8.5%;102MG/100ML;45MG/100ML; 522MG/100ML;410MG/100ML¤ N19437 005 APR 03, 1986

AMINOSYN II 10% W/ ELECTROLYTES
ABBOTT LABORATORIES 10%;102MG/100ML;45MG/100ML; 522MG/100ML;410MG/100ML¤ N19437 004 APR 03, 1986

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-9)

INJECTABLE; INJECTION

/TRAVASOL M 3.5% W/ ELECTROLYTE 4S/
TRAVASOL 3.5% W/ ELECTROLYTES
TRAVENOL LABS 3.5%;51MG/100ML;131MG/100ML; 218MG/100ML;35MG/100ML N17493 003

> ADD > AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;
> ADD > SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC; (PAGE 3-9)

> ADD > INJECTABLE; INJECTION
> ADD > AMINOSYN II 3.5% M
> ADD > ABBOTT LABORATORIES 3.5%;30MG/100ML;97MG/100ML;
> ADD > 120MG/100ML;49MG/100ML¤ N19437 007
> ADD > APR 03, 1986

AMINOCAPROIC ACID (PAGE 3-9)

INJECTABLE; INJECTION

AMINOCAPROIC ACID

AP	LYPHOMED	250MG/ML¤	N70522 001 JUN 17, 1986
AP	QUAD PHARMS	250MG/ML¤	N70694 001 MAR 04, 1986

AMINOPHYLLINE (PAGE 3-10)

TABLET; ORAL

AMINOPHYLLINE

AB	CORD LABORATORIES	100MG	N85262 002
/BD/	/CORD LABORATORIES/	/100MG/	/N85262 002/

AMIODARONE HYDROCHLORIDE (PAGE 3-11)

TABLET; ORAL

CORDARONE

	IVES LABS/AMHO	200MG¤	N18972 001 DEC 24, 1985

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE (PAGE 3-14)

TABLET; ORAL

> ADD > CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

> ADD > AB	BARR LABORATORIES	EQ 12.5MG BASE;5MG¤	N70765 001 DEC 10, 1986
> ADD > AB		EQ 25MG BASE;10MG¤	N70766 001 DEC 10, 1986
> ADD > AB	MYLAN PHARMS	EQ 12.5MG BASE;5MG¤	N71296 001 DEC 10, 1986
> ADD > AB		EQ 25MG BASE;10MG¤	N71297 001 DEC 10, 1986

LIMBITROL

	/HOFFMANN-LA ROCHE	/12.5MG;5MG/ /25MG;10MG/	/N16949 001/ /N16949 002/
> ADD > AB	HOFFMANN-LA ROCHE	EQ 12.5MG BASE;5MG	N16949 001
> ADD > AB		EQ 25MG BASE;10MG	N16949 002

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

AB	BARR LABORATORIES	10MG;2MG¤	N71077 001 NOV 12, 1986
AB		25MG;2MG¤	N70297 001 NOV 12, 1986
AB		10MG;4MG¤	N71078 001 NOV 12, 1986
AB		25MG;4MG¤	N71079 001 NOV 12, 1986

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

AB	BOLAR PHARMACEUTICAL	10MG;2MG¤	N70373 001 AUG 25, 1986
AB		25MG;2MG¤	N70374 001 AUG 25, 1986
AB		10MG;4MG¤	N70375 001 AUG 25, 1986
AB		25MG;4MG¤	N70376 001 AUG 25, 1986
AB		50MG;4MG¤	N70377 001 NOV 04, 1986
AB	CHELSEA LABORATORIES	10MG;2MG¤	N71384 001 NOV 03, 1986
AB		25MG;2MG¤	N71385 001 NOV 03, 1986
AB		10MG;4MG¤	N71386 001 NOV 03, 1986
AB		25MG;4MG¤	N71387 001 NOV 03, 1986
AB	PAR PHARMACEUTICAL	10MG;2MG¤	N70565 001 SEP 11, 1986
AB		25MG;2MG¤	N70621 001 SEP 11, 1986
AB		10MG;4MG¤	N70620 001 SEP 11, 1986
AB		25MG;4MG¤	N70595 001 SEP 11, 1986
AB		50MG;4MG¤	N70574 001 SEP 11, 1986
AB	ZENITH LABORATORIES	10MG;2MG¤	N70935 001 SEP 11, 1986
AB		25MG;2MG¤	N70936 001 SEP 11, 1986
AB		10MG;4MG¤	N70937 001 SEP 11, 1986
AB		25MG;4MG¤	N70938 001 SEP 11, 1986
AB		50MG;4MG¤	N70939 001 SEP 12, 1986

TRIAVIL 2-10

/BP/ /MS&D/MERCK/ /10MG;2MG/ /N14715.004/

TRIAVIL 2-25

/BP/ /MS&D/MERCK/ /25MG;2MG/ /N14715.002/

TRIAVIL 4-10

/BP/ /MS&D/MERCK/ /10MG;4MG/ /N14715.001/

/BP/ /MS&D/MERCK/ /10MG;4MG/ /N14715.003/

TRIAVIL 4-25

/BP/ /MS&D/MERCK/ /25MG;4MG/ /N14715.005/

TRIAVIL 4-50

/BP/ /MS&D/MERCK/ /50MG;4MG/ /N14715.006/

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

TABLET; ORAL

TRIAVIL 2-10

AB	MS&D/MERCK	10MG;2MG	N14715 004

TRIAVIL 2-25

AB	MS&D/MERCK	25MG;2MG	N14715 002

TRIAVIL 4-10

AB	MS&D/MERCK	10MG;4MG	N14715 003

TRIAVIL 4-25

AB	MS&D/MERCK	25MG;4MG	N14715 005

TRIAVIL 4-50

AB	MS&D/MERCK	50MG;4MG	N14715 006

AMOXICILLIN (PAGE 3-15)

CAPSULE; ORAL

AMOXICILLIN

AB	LABORATORIOS ATRAL	250MG¤	N62528 001 AUG 07, 1985
AB		500MG¤	N62528 002 AUG 07, 1985

UTIMOX

AB	/S/PARKE-DAVIS/W-L	250MG	N62107 001
AB	/S/	500MG	N62107 002

POWDER FOR RECONSTITUTION; ORAL

UTIMOX

AB	PARKE-DAVIS/W-L	125MG/5ML	N62127 001
AB		250MG/5ML	N62127 002

AMPICILLIN SODIUM (PAGE 3-17)

INJECTABLE; INJECTION

AMPICILLIN SODIUM

AP	ELI LILLY	EQ 2GM BASE/VIAL¤	N62565 003 JUN 24, 1986
AP	ELKINS-SINN/AHROBINS	EQ 125MG BASE/VIAL¤	N62692 001 JUN 24, 1986
AP		EQ 250MG BASE/VIAL¤	N62692 002 JUN 24, 1986
AP		EQ 500MG BASE/VIAL¤	N62692 003 JUN 24, 1986
AP		EQ 1GM BASE/VIAL¤	N62692 004 JUN 24, 1986
AP		EQ 2GM BASE/VIAL¤	N62692 005 JUN 24, 1986
AP		EQ 10GM BASE/VIAL¤	N62692 006 JUN 24, 1986

AMPICILLIN SODIUM (PAGE 3-17)

INJECTABLE; INJECTION

OMNIPEN-N

> ADD >	AP	WYETH LABS/AMHO	EQ 125MG BASE/VIAL¤	N62718 001
> ADD >				DEC 16, 1986
> ADD >	AP		EQ 250MG BASE/VIAL¤	N62718 002
> ADD >				DEC 16, 1986
> ADD >	AP		EQ 500MG BASE/VIAL¤	N62718 003
> ADD >				DEC 16, 1986
> ADD >	AP		EQ 1GM BASE/VIAL¤	N62718 004
> ADD >				DEC 16, 1986
> ADD >	AP		EQ 2GM BASE/VIAL¤	N62718 005
> ADD >				DEC 16, 1986

TOTACILLIN-N

> ADD >	AP	BEECHAM LABS/BEECHAM	EQ 1GM BASE/VIAL¤	N62727 001
> ADD >				DEC 19, 1986
> ADD >	AP		EQ 2GM BASE/VIAL¤	N62727 002
> ADD >				DEC 19, 1986
	AP		EQ 10GM BASE/VIAL	N60677 006

> ADD > AMPICILLIN SODIUM; SULBACTAM SODIUM (PAGE 3-18)

> ADD > INJECTABLE; INJECTION

> ADD > UNASYN

> ADD >	PFIZER LABS/PFIZER	EQ 500MG BASE/VIAL;	
> ADD >		EQ 250MG BASE/VIAL	N50608 003
> ADD >			DEC 31, 1986
> ADD >		EQ 1GM BASE/VIAL;	
> ADD >		EQ 500MG BASE/VIAL	N50608 002
> ADD >			DEC 31, 1986
> ADD >		EQ 2GM BASE/VIAL;	
> ADD >		EQ 1GM BASE/VIAL	N50608 001
> ADD >			DEC 31, 1986

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN A; VITAMINE E (PAGE 3-19)

INJECTABLE; INJECTION

M.V.I.-12 LYOPHILIZED

USV PHARMACEUTICAL	100MG/VIAL;0.06MG/VIAL;0.05MG/VIAL 15MG/VIAL;200 IU/VIAL;0.4MG/VIAL; 40MG/VIAL;4MG/VIAL;3.6MG/VIAL; 3MG/VIAL;3,300 IU/VIAL;10 IU/VIAL¤	N18933 002 AUG 08, 1985

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E (PAGE 3-19)

INJECTABLE; INJECTION

M.V.C. 9+3

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 IU/ML;1 IU/ML¤	N18440 002 AUG 08, 1985

M.V.I.-12

AP	USV PHARMACEUTICAL	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 IU/ML;1 IU/ML¤	N08809 004 AUG 08, 1985

MVC PLUS

AP	ASCOT HOSP PHARMS	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 IU/ML;1 IU/ML¤	N18439 002 AUG 08, 1985

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN E (PAGE 3-19)

INJECTABLE; INJECTION

BEROCCA PN

HOFFMANN-LA ROCHE	50MG/ML;0.03MG/ML;0.0025MG/ML; 7.5MG/ML;100 IU/ML;0.2MG/ML;20MG/ML; 2MG/ML;1.8MG/ML;1.5MG/ML;1,650 IU/ML; 5 IU/ML¤	N06071 003 OCT 10, 1985

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)

CAPSULE; ORAL

BUTALBITAL W/ ASPIRIN AND CAFFEINE

AB	CHELSEA LABORATORIES	325MG;50MG;40MG	N86231 002 FEB 12, 1985

FIORINAL

AB	SANDOZ PHARMS/SANDOZ	325MG;50MG;40MG¤	N17534 005 APR 16, 1986

LANORINAL

AB	LANNETT	325MG;50MG;40MG¤	N86996 002 OCT 11, 1985

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)

TABLET; ORAL

	BUTALBITAL W/ ASPIRIN AND CAFFEINE			
AB	WEST-WARD	325MG;50MG;40MG	N86162 002	FEB 16, 1984
> ADD >	**BUTALBITAL, ASPIRIN & CAFFEINE**			
> ADD > AB	HALSEY DRUG	325MG;50MG;40MG¤	N89448 001	DEC 01, 1986
> ADD >				
	FIORINAL			
AB	SANDOZ PHARMS/SANDOZ	325MG;50MG;40MG¤	N17534 003	APR 16, 1986
	LANORINAL			
AB	LANNETT	325MG;50MG;40MG¤	N86986 002	OCT 18, 1985

ASPIRIN; CARISOPRODOL (PAGE 3-20)

TABLET; ORAL

	CARISOPRODOL COMPOUND			
AB	BOLAR PHARMACEUTICAL	325MG;200MG¤	N88809 001	OCT 03, 1985
	SOMA COMPOUND			
AB	WALLACE PHARMS/C-W	325MG;200MG	N12365 005	JUL 11, 1983

ASPIRIN; MEPROBAMATE (PAGE 3-20)

TABLET; ORAL

	MEPROBAMATE AND ASPIRIN			
AB	PAR PHARMACEUTICAL	325MG;200MG¤	N89126 001	AUG 19, 1986

ASPIRIN; METHOCARBAMOL (PAGE 3-20)

TABLET; ORAL

	METHOCARBAMOL AND ASPIRIN			
AB	MCNEIL CONSUMER PROD	325MG;400MG¤	N89193 001	FEB 12, 1986

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE (PAGE 3-20)

TABLET; ORAL

	/OXYCODONE AND ASPIRIN (FULL-STRENGTH)/			
	ROXIPRIN			
AA	ROXANE LABORATORIES	325MG;4.5MG;0.38MG	N87743 001	JUN 04, 1982

> ADD > AZTREONAM (PAGE 3-22)

> ADD > INJECTABLE; INJECTION

> ADD > AZACTAM

> ADD >	ER SQUIBB AND SONS	500MG/VIAL¤	N50580 001
> ADD >			DEC 31, 1986
> ADD >		1GM/VIAL¤	N50580 002
> ADD >			DEC 31, 1986
> ADD >		2GM/VIAL¤	N50580 003
> ADD >			DEC 31, 1986

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-23)

OINTMENT; TOPICAL

	CORTISPORIN		
AT	BURROUGHS WELLCOME	400 UNITS/GM;1%;EQ 3.5MG BASE/GM; 5,000 UNITS/GM	N50168 002 MAY 04, 1985
	NEOMYCIN & POLYMYXIN B SULFATES & BACITRACIN ZINC & HYDROCORTISONE		
AT	PHARMAFAIR	400 UNITS/GM;1%;EQ 3.5MG BASE/GM; 5,000 UNITS/GM¤	N62381 001 SEP 06, 1985

BENZYL PENICILLOYL-POLYLYSINE (PAGE 3-25)

INJECTABLE; INJECTION

PRE-PEN		
/KREMERS-URBAN/	/60 UMOLAR/	/N50114 001/
SCHWARZ PHARMS	60 UMOLAR	N50114 001

BETAMETHASONE BENZOATE (PAGE 3-25)

CREAM; TOPICAL

/BENISONE/		
/PARKE-DAVIS/W-L/	/0.025%/	/N16998 001/
UTICORT		
PARKE-DAVIS/W-L	0.025%	N16998 002

GEL; TOPICAL
/BENISONE/
UTICORT

OINTMENT: TOPICAL
/BENISONE/
UTICORT

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

CREAM; TOPICAL
DIPROLENE

BX	SCHERING	EQ 0.05% BASE¤	N19408 001 JAN 31, 1986

LOTION; TOPICAL
ALPHATREX

AB	SAVAGE LABS/ALTANA	EQ 0.05% BASE¤	N70273 001 AUG 12, 1985

BETAMETHASONE DIPROPIONATE

AB	E FOUGERA/ALTANA	EQ 0.05% BASE¤	N70275 001 AUG 12, 1985
AB	PHARMADERM/ALTANA	EQ 0.05% BASE¤	N70274 001 AUG 12, 1985

BETAMETHASONE VALERATE (PAGE 3-26)

CREAM; TOPICAL
BETAMETHASONE VALERATE

AB	CLAY-PARK LABS	EQ 0.1% BASE¤	N70053 001 JUN 10, 1986

OINTMENT; TOPICAL
BETA-VAL

AB	LEMMON	EQ 0.1% BASE¤	N70069 001 DEC 19, 1985

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC
BETOPTIC

	ALCON LABORATORIES	EQ 0.5% BASE¤	N19270 001 AUG 30, 1985

BETHANECHOL CHLORIDE (PAGE 3-27)

TABLET; ORAL
BETHANECHOL CHLORIDE

AA	SIDMAK LABORATORIES	5MG¤	N89095 001 DEC 19, 1985
AA		50MG¤	N89096 001 DEC 19, 1985

BRETYLIUM TOSYLATE (PAGE 3-28)

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE

AP	ABBOTT LABORATORIES	50MG/ML¤	N19033 001 APR 29, 1986 : APR 16, 1986
AP	ELKINS-SINN/AHROBINS	50MG/ML¤	N70545 001 MAY 14, 1986
AP		50MG/ML¤	N70546 001 MAY 14, 1986
AP	INTL MEDICATION SYS	50MG/ML¤	N70119 001 APR 29, 1986 : MAR 06, 1986
AP	LYPHOMED	50MG/ML¤	N70134 001 APR 29, 1986 : FEB 12, 1986

BRETYLIUM TOSYLATE IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	50MG/ML¤	N19030 001 APR 29, 1986 : APR 16, 1986

BRETYLOL

AP	AM CRITICAL CARE/AHS	50MG/ML	N17954 001

BRETYLIUM TOSYLATE; DEXTROSE (PAGE 3-28)

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE IN DEXTROSE 5%

AP	ABBOTT LABORATORIES	200MG/100ML;5GM/100ML¤	N19005 002 APR 29, 1986 : APR 16, 1986
AP		400MG/100ML;5GM/100ML¤	N19005 003 APR 29, 1986 : APR 16, 1986
AP		800MG/100MG;5GM/100ML¤	N19005 001 APR 29, 1986 : APR 16, 1986

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	200MG/100ML;5GM/100ML¤	N19008 002 APR 29, 1986 : APR 16, 1986
AP		400MG/100ML;5GM/100ML¤	N19008 003 APR 29, 1986 : APR 16, 1986
AP		800MG/100MG;5GM/100ML¤	N19008 001 APR 29, 1986 : APR 16, 1986
	KENDALL MCGAW LABS	100MG/100ML;5GM/100ML¤	N19121 001 APR 29, 1986
AP		200MG/100ML;5GM/100ML¤	N19121 002 APR 29, 1986
AP		400MG/100ML;5GM/100ML¤	N19121 003 APR 29, 1986

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-28)

SYRUP; ORAL
AMBENYL

AA	FOREST LABORATORIES	12.5MG/5ML;10MG/5ML		N09319 006 JAN 10, 1984

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-29)

TABLET, CONTROLLED RELEASE; ORAL
DIMETAPP
AH ROBINS 12MG;75MG N12436 002 APR 02, 1984

BUPIVACAINE HYDROCHLORIDE (PAGE 3-29)

INJECTABLE; INJECTION
SENSORCAINE

AP	ASTRA PHARM PRODS	0.25%		N70552 001 MAY 21, 1986
AP		0.5%		N70553 001 MAY 21, 1986
AP		0.75%		N70554 001 MAY 21, 1986

BUPIVACAINE HYDROCHLORIDE; DEXTROSE (PAGE 3-29)

INJECTABLE; INJECTION
MARCAINE SPINAL

∂	WINTHROP-BREON/STERL	0.75%;8.25%		N18692 001 MAY 04, 1984

BUPROPION HYDROCHLORIDE (PAGE 3-30)

TABLET; ORAL
WELLBUTRIN

∂	BURROUGHS WELLCOME	50MG		N18644 001 DEC 30, 1985
∂		75MG		N18644 002 DEC 30, 1985
∂		100MG		N18644 003 DEC 30, 1985

BUSPIRONE HYDROCHLORIDE (PAGE 3-30)

TABLET; ORAL
BUSPAR

	BRISTOL LABS/B-M	5MG		N18731 001 SEP 29, 1986
		10MG		N18731 002 SEP 29, 1986

BUTOCONAZOLE NITRATE (PAGE 3-31)

CREAM; VAGINAL
FEMSTAT

	SYNTEX LABS/SYNTEX	2%		N19215 001 NOV 25, 1985

SUPPOSITORY; VAGINAL
FEMSTAT

	SYNTEX LABS/SYNTEX	100MG		N19359 001 NOV 25, 1985

CALCEFEDIOL; ANHYDROUS (PAGE 3-31)
CALCIFEDIOL, ANHYDROUS (PAGE 3-31)

CALCITONIN, HUMAN (PAGE3-31)

INJECTABLE; INJECTION
CIBACALCIN

	CIBA/CIBA-GEIGY	0.5MG/VIAL		N18470 001 OCT 31, 1986

CALCITONIN, SALMON (PAGE 3-31)

INJECTABLE; INJECTION
MIACALCIN

	SANDOZ PHARMS/SANDOZ	100 IU/ML		N17808 001 JUL 03, 1986

CALCITROL (PAGE 3-31)

INJECTABLE; INJECTION
CALCIJEX

	ABBOTT LABORATORIES	0.001MG/ML		N18874 001 SEP 25, 1986
		0.002MG/ML		N18874 002 SEP 25, 1986

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-32)

SOLUTION; INTRAPERITONEAL
DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
KENDALL MCGAW LABS 29MG/100ML;2.5GM/100ML; 15MG/100ML;610MG/100ML; 560MG/100ML¤ N18460 006 JAN 29, 1986

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-32)

SOLUTION; INTRAPERITONEAL
DIALYTE W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
KENDALL MCGAW LABS 26MG/100ML;1.5GM/100ML; 5MG/100ML;530MG/100ML; 450MG/100ML¤ N18460 007 JAN 29, 1986

DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
KENDALL MCGAW LABS 26MG/100ML;2.5GM/100ML; 5MG/100ML;530MG/100ML; 450MG/100ML¤ N18460 008 JAN 29, 1986

DIALYTE W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
KENDALL MCGAW LABS 26MG/100ML;4.25GM/100ML; 5MG/100ML;530MG/100ML; 450MG/100ML¤ N18460 009 JAN 29, 1986

DIANEAL PD-1 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
TRAVENOL LABS 25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML¤ N17512 010 NOV 18, 1985

DIANEAL PD-2 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
TRAVENOL LABS 25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538/100ML; 448MG/100ML¤ N17512 011 NOV 18, 1985

CALCIUM CHLORIDE; DEXTROSE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-32)

SOLUTION; INTRAPERITONEAL
INPERSOL-ZM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 25.7MG/100ML;1.5GM/100ML; 538MG/100ML;448MG/100ML¤ N19395 001 MAR 26, 1986

INPERSOL-ZM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 25.7MG/100ML;2.5GM/100ML; 538MG/100ML;448MG/100ML¤ N19395 002 MAR 26, 1986

CALCIUM CHLORIDE; DEXTROSE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-32)

SOLUTION; INTRAPERITONEAL
INPERSOL-ZM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 25.7MG/100ML;4.25GM/100ML; 538MG/100ML;448MG/100ML¤ N19395 003 MAR 26, 1986

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-34)

INJECTABLE; INJECTION
TPN ELECTROLYTES IN PLASTIC CONTAINER
ABBOTT LABORATORIES 16.5MG/ML;25.4MG/ML;74.6MG/ML; 121MG/ML;16.1MG/ML¤ N19399 001 JUN 16, 1986
16.5MG/ML;25.4MG/ML;74.6MG/ML; 121MG/ML;16.1MG/ML N18895 001 JUL 20, 1984

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-35)

INJECTABLE; INJECTION
LACTATED RINGER'S IN PLASTIC CONTAINER
AP ABBOTT LABORATORIES 20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML¤ N19485 001 OCT 24, 1985

SOLUTION; IRRIGATION
LACTATED RINGER'S IN PLASTIC CONTAINER
AT ABBOTT LABORATORIES 20MG/100ML;30MG/100ML;600MG/100ML 310MG/100ML¤ N19416 001 JAN 17, 1986

CAPTOPRIL (PAGE 3-36)

TABLET; ORAL
CAPOTEN
ER SQUIBB AND SONS 37.5MG¤ N18343 006 SEP 17, 1986

CARBACHOL (PAGE 3-36)

INJECTABLE; INJECTION
CARBACHOL
AP PHARMAFAIR 0.01%¤ N70292 001 MAY 21, 1986

MIOSTAT
AP ALCON LABORATORIES 0.01% N16968 001

CARBAMAZEPINE (PAGE 3-36)

TABLET; ORAL

CARBAMAZEPINE			
AB	COLMED LABORATORIES	200MG¤	N70300 001 MAY 15, 1986
AB	INWOOD LABS/FOREST	200MG¤	N70231 001 AUG 14, 1986
EPITOL			
AB	LEMMON	200MG¤	N70541 001 SEP 17, 1986
TEGRETOL			
AB	GEIGY/CIBA-GEIGY	200MG	N16608 001

CARNITINE, L- (PAGE 3-37)

SOLUTION; ORAL

VITACARN			
	KENDALL MCGAW LABS	1GM/10ML¤	N19257 001 APR 10, 1986

TABLET; ORAL

/L-CARNITINE/			
CARNITOR			
	SIGMA-TAU	330MG¤	N18948 001 DEC 27, 1985

CEFAMANDOLE NAFATE (PAGE 3-37)

INJECTABLE; INJECTION

MANDOL			
	ELI LILLY	EQ 1GM BASE/VIAL¤	N62560 001 SEP 10, 1985
		EQ 2GM BASE/VIAL¤	N62560 002 SEP 10, 1985

CEFAZOLIN SODIUM (PAGE 3-38)

INJECTABLE; INJECTION

CEFAZOLIN SODIUM			
AP	LYPHOMED	EQ 500MG BASE/VIAL¤	N62688 002 NOV 17, 1986
AP		EQ 1GM BASE/VIAL¤	N62688 003 NOV 17, 1986
AP		EQ 10GM BASE/VIAL¤	N62688 004 NOV 17, 1986

CEFAZOLIN SODIUM (PAGE 3-38)

INJECTABLE; INJECTION

KEFZOL			
AP	ELI LILLY	EQ 500MG BASE/VIAL¤	N62557 001 SEP 10, 1985
AP		EQ 1GM BASE/VIAL¤	N62557 002 SEP 10, 1985

CEFOPERAZONE SODIUM; DEXTROSE (PAGE 3-38)

INJECTABLE; INJECTION

CEFOBID IN PLASTIC CONTAINER			
	ROERIG/PFIZER	EQ 40MG BASE/ML;36MG/ML¤	N50613 001 JUL 23, 1986

CEFOTETAN DISODIUM (PAGE 3-38)

INJECTABLE; INJECTION

CEFOTAN			
	STUART PHARMS/ICI	EQ 1GM BASE/VIAL¤	N50588 001 DEC 27, 1985
		EQ 2GM BASE/VIAL¤	N50588 002 DEC 27, 1985

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION

FORTAZ			
AP	GLAXO	500MG/VIAL	N50578 001 JUL 19, 1985
AP		1GM/VIAL	N50578 002 JUL 19, 1985
AP		2GM/VIAL	N50578 003 JUL 19, 1985
AP		6GM/VIAL	N50578 004 JUL 19, 1985
TAZICEF			
AP	SK&F LABORATORIES	500MG/VIAL¤	N62662 001 MAR 06, 1986
AP		1GM/VIAL¤	N62662 002 MAR 06, 1986
AP		2GM/VIAL¤	N62662 003 MAR 06, 1986
AP		6GM/VIAL¤	N62662 004 MAR 06, 1986

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION

	TAZIDIME		
AP	ELI LILLY	500MG/VIAL¤	N62640 001 NOV 20, 1985
AP		1GM/VIAL¤	N62640 002 NOV 20, 1985
AP		1GM/VIAL¤	N62655 001 NOV 20, 1985
AP		2GM/VIAL¤	N62655 002 NOV 20, 1985
AP		2GM/VIAL¤	N62640 003 NOV 20, 1985
	TAZIDIME IN PLASTIC CONTAINER		
AP	ELI LILLY	1GM/VIAL¤	N62739 001 JUL 10, 1986
AP		2GM/VIAL¤	N62739 002 JUL 10, 1986

CEFUROXIME SODIUM (PAGE 3-40)

INJECTABLE; INJECTION

	KEFUROX		
AP	ELI LILLY	EQ 750MG BASE/VIAL¤	N62591 001 JAN 10, 1986
AP		EQ 750MG BASE/VIAL¤	N62592 001 JAN 10, 1986
AP		EQ 1.5GM BASE/VIAL¤	N62591 002 JAN 10, 1986
AP		EQ 1.5GM BASE/VIAL¤	N62592 002 JAN 10, 1986
	KEFUROX IN PLASTIC CONTAINER		
AP	ELI LILLY	EQ 750MG BASE/VIAL¤	N62590 001 JAN 10, 1986
AP		EQ 1.5GM BASE/VIAL¤	N62590 002 JAN 10, 1986
	ZINACEF		
AP	GLAXO	EQ 750MG BASE/VIAL	N50558 002 OCT 19, 1983
AP		EQ 1.5 GM BASE/VIAL	N50558 003 OCT 19, 1986

CEPHALEXIN (PAGE 3-40)

TABLET; ORAL

	KEFLET		
>ADD>	ELI LILLY	EQ 250MG BASE¤	N62745 001 DEC 01, 1986
>ADD>		EQ 500MG BASE¤	N62745 002 DEC 01, 1986

CEPHALOTHIN SODIUM (PAGE 3-40)

INJECTABLE; INJECTION

	CEPHALOTHIN SODIUM		
AP	ABBOTT LABORATORIES	EQ 1GM BASE/VIAL¤	N62547 001 SEP 11, 1985
AP		EQ 1GM BASE/VIAL¤	N62548 001 SEP 11, 1985
AP		EQ 2GM BASE/VIAL¤	N62547 002 SEP 11, 1985
AP		EQ 2GM BASE/VIAL¤	N62548 002 SEP 11, 1985
	KEFLIN IN PLASTIC CONTAINER		
AP	ELI LILLY	EQ 1GM BASE/VIAL¤	N62549 001 SEP 10, 1985
AP		EQ 2GM BASE/VIAL¤	N62549 002 SEP 10, 1985

CEPHAPIRIN SODIUM (PAGE 3-41)

INJECTABLE; INJECTION

		CEFADYL		
AP		BRISTOL LABS/B-M	EQ 500MG BASE/VIAL	N50446 005
AP			EQ 1GM BASE/VIAL	N50446 001
AP			EQ 1GM BASE/VIAL	N61769 001
>ADD> AP			EQ 1GM BASE/VIAL	N62724 001 DEC 23, 1986
AP			EQ 2GM BASE/VIAL	N50446 002
AP			EQ 2GM BASE/VIAL	N61769 002
>ADD> AP			EQ 2GM BASE/VIAL	N62724 002 DEC 23, 1986
AP			EQ 4GM BASE/VIAL	N50446 003
AP			EQ 20GM BASE/VIAL	N50446 004
		CEPHAPIRIN SODIUM		
AP		LYPHOMED	EQ 500MG BASE/VIAL¤	N62723 001 NOV 17, 1986
AP			EQ 1GM BASE/VIAL¤	N62723 002 NOV 17, 1986
AP			EQ 2GM BASE/VIAL¤	N62723 003 NOV 17, 1986
AP			EQ 4GM BASE/VIAL¤	N62723 004 NOV 17, 1986
AP			EQ 20GM BASE/VIAL¤	N62723 005 NOV 17, 1986

CHLORAMPHENICOL (PAGE 3-42)

SOLUTION/DROPS; OPHTHALMIC
CHLORAMPHENICOL

AT	CARTER-GLOGAU LABS	0.5%¤	N62628 001	SEP 25, 1985

CHLORHEXIDINE GLUCONATE (PAGE 3-44)

SOLUTION; DENTAL
PERIDEX

	PROCTER AND GAMBLE	0.12%¤	N19028 001	AUG 13, 1986

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-46)

CAPSULE, CONTROLLED RELEASE; ORAL
DRIZE

BC	BF ASCHER	12MG;75MG¤	N88359 001	FEB 13, 1986

ORNADE

BC	SK&F LABORATORIES	12MG;75MG	N12152 004	

CHLORPROPAMIDE (PAGE 3-48)

TABLET; ORAL
CHLORPROPAMIDE

AB	BARR LABORATORIES	100MG¤	N89446 001	NOV 17, 1986
AB		250MG¤	N89447 001	NOV 17, 1986
AB	HALSEY DRUG	100MG¤	N89321 001	JAN 16, 1986
AB		250MG¤	N88662 001	JAN 09, 1986

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL
CHLORTHALIDONE

AB	MUTUAL PHARM	25MG¤	N89285 001	JUL 21, 1986
AB		50MG¤	N89286 001	JUL 21, 1986

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL
CHLORTHALIDONE

AB	PUREPAC/KALIPHARMA	25MG¤	N89139 001	JUL 16, 1986
AB	SIDMAK LABORATORIES	25MG¤	N88902 001	SEP 19, 1985
AB		50MG¤	N88903 001	SEP 19, 1985

CHROMIC CHLORIDE (PAGE 3-50)

INJECTABLE; INJECTION
CHROMIC CHLORIDE IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	EQ 0.004MG CHROMIUM/ML¤	N18961 001 JUN 26, 1986

CHYMOPAPAIN (PAGE 3-50)

INJECTABLE; INJECTION
CHYMODIACTIN

	/SMITH LABORATORIES/	/4,000 UNITS/VIAL/	/N18663 002/ /AUG 21, 1984/
		/10,000 UNITS/VIAL/	/N18663 001/ /NOV 10, 1982/
	TRAVENOL LABS	4,000 UNITS/VIAL	N18663 002 AUG 21, 1984
		10,000 UNITS/VIAL	N18663 001 NOV 10, 1982

CILASTATIN SODIUM; IMIPENEM (PAGE 3-50)

INJECTABLE; INJECTION
PRIMAXIN

	MS&D RES LABS/MERCK	EQ 250MG BASE/VIAL; 250MG/VIAL¤	N50587 001 NOV 26, 1985
		EQ 500MG BASE/VIAL; 500MG/VIAL¤	N50587 002 NOV 26, 1985

CIMETIDINE (PAGE 3-50)

TABLET; ORAL
TAGAMET

	SK&F LAB	800MG¤	N17920 005 APR 30, 1986

CIMETIDINE HYDROCHLORIDE; SODIUM CHLORIDE (PAGE 3-50)

INJECTABLE; INJECTION
TAGAMET IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

	SK&F LAB	EQ 6MG BASE/ML;9MG/ML¤	N19434 001	OCT 31, 1985

CLINDAMYCIN PALMITATE HYDROCHLORIDE (PAGE 3-51)

POWDER FOR RECONSTITUTION; ORAL
CLEOCIN

AA	UPJOHN	EQ 75MG BASE/5ML¤	N62644 001	APR 07, 1986
AA	UPJOHN MANUFACTURING	EQ 75MG BASE/5ML	N61827 001	

CLOBETASOL PROPIONATE (PAGE 3-51)

CREAM; TOPICAL
TEMOVATE

	GLAXO	0.05%¤	N19322 001	DEC 27, 1985

OINTMENT; TOPICAL
TEMOVATE

	GLAXO	0.05%¤	N19323 001	DEC 27, 1985

> ADD > CLOFAZIMINE (PAGE 3-51)

> ADD > CAPSULE; ORAL
> ADD > LAMPRENE

> ADD >	GEIGY/CIBA-GEIGY	50MG¤	N19500 002	DEC 15, 1986
> ADD >		100MG¤	N19500 001	DEC 15, 1986

CLOFIBRATE (PAGE 3-51)

CAPSULE; ORAL
ATROMID-S

AB	AYERST LABS/AMHO	500MG	N16099 002	

CLOFIBRATE

AB	FORMUTEC	500MG¤	N70531 001	JUN 16, 1986

CLONAZEPAM (PAGE 3-52)

TABLET; ORAL
/CLONOPIN/
KLONOPIN

HOFFMANN-LA ROCHE	0.5MG	N17533 001	
	1MG	N17533 002	
	2MG	N17533 003	

CLONIDINE HYDROCHLORIDE (PAGE 3-52)

TABLET; ORAL
CATAPRES

AB	BOEHRINGER INGELHEIM	0.1MG	N17407 001	
AB		0.2MG	N17407 002	
AB		0.3MG	N17407 003	

CLONIDINE HCL

AB	AM THERAPEUTICS	0.1MG¤	N70881 001	JUL 08, 1986 : MAY 27, 1986
AB		0.2MG¤	N70882 001	JUL 08, 1986 : MAY 27, 1986
AB		0.3MG¤	N70883 001	JUL 08, 1986 : MAY 27, 1986
AB	BIOCRAFT LABS	0.1MG¤	N70747 001	JUL 08, 1986 : MAR 20, 1986
AB		0.2MG¤	N70702 001	JUL 08, 1986 : MAR 20, 1986
AB		0.3MG¤	N70659 001	JUL 08, 1986 : MAR 20, 1986
AB	DANBURY PHARMACAL	0.1MG¤	N70965 001	JUL 08, 1986 : JUL 01, 1986
AB		0.2MG¤	N70964 001	JUL 08, 1986 : JUL 01, 1986
AB		0.3MG¤	N70963 001	JUL 08, 1986 : JUL 01, 1986
AB	DURAMED PHARMS	0.1MG¤	N71103 001	AUG 14, 1986
AB		0.2MG¤	N71102 001	AUG 14, 1986
AB		0.3MG¤	N71101 001	AUG 14, 1986
AB	INTERPHARM	0.1MG¤	N71252 001	OCT 01, 1986
AB		0.2MG¤	N71253 001	OCT 01, 1986
AB		0.3MG¤	N71254 001	OCT 01, 1986
AB	PAR PHARMACEUTICAL	0.1MG¤	N70461 001	JUL 08, 1986 : NOV 22, 1985
AB		0.2MG¤	N70460 001	JUL 08, 1986 : NOV 22, 1985
AB		0.3MG¤	N70459 001	JUL 08, 1986 : NOV 22, 1985
> ADD > AB	PUREPAC/KALIPHARMA	0.1MG¤	N70974 001	DEC 16, 1986
> ADD > AB		0.2MG¤	N70975 001	DEC 16, 1986
> ADD > AB		0.3MG¤	N70976 001	DEC 16, 1986

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-53)

SYRUP; ORAL
PROMETHAZINE VC W/ CODEINE

AA	HR CENCI LABS	10MG/5ML;5MG/5ML; 6.25MG/5ML¤	N88816 001	NOV 22, 1985

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-53)

SYRUP; ORAL
PROMETHAZINE W/ CODEINE

AA	HR CENCI LABS	10MG/5ML;6.25MG/5ML¤	N88814 001	NOV 22, 1985

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-53)

SYRUP; ORAL
HISTAFED C

AA	LIFE LABORATORIES	10MG/5ML;30MG/5ML; 1.25MG/5ML¤	N89018 001	JUL 23, 1986

COPPER (PAGE 3-54)

INTRAUTERINE DEVICE; INTRAUTERINE
CU-7

∂	SEARLE PHARMS	89MG	N17408 001

TATUM-T

∂	SEARLE PHARMS	120MG	N18205 001

CROMOLYN SODIUM (PAGE 3-55)

AEROSOL; INHALATION
INTAL

	FISONS	0.8MG/INH¤	N18887 001 DEC 05, 1985

CUPRIC CHLORIDE (PAGE 3-55)

INJECTABLE; INJECTION
CUPRIC CHLORIDE IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	EQ 0.4MG COPPER/ML¤	N18960 001 JUN 26, 1986

CYCLOPHOSPHAMIDE (PAGE 3-57)

INJECTABLE; INJECTION
CYCLOPHOSPHAMIDE

AP	ELKINS-SINN/AHROBINS	100MG/VIAL¤	N88371 001	JUL 03, 1986
AP		200MG/VIAL¤	N88372 001	JUL 03, 1986
AP		500MG/VIAL¤	N88373 001	JUL 03, 1986
AP		1GM/VIAL¤	N88374 001	SEP 24, 1986 : JUL 03, 1986

CYTOXAN

AP	BRISTOL LABS/B-M	2GM/VIAL	N12142 005	AUG 30, 1982

LYOPHILIZED CYCLOPHOSPHAMIDE

AP	LYPHOMED	100MG/VIAL¤	N89194 001	AUG 27, 2002 : JUL 07, 1986
AP		200MG/VIAL¤	N89195 001	AUG 27, 2002 : JUL 07, 1986
AP		500MG/VIAL¤	N89196 001	AUG 27, 2002 : JUL 07, 1986

LYOPHILIZED CYTOXAN

AP	BRISTOL LABS/B-M	100MG/VIAL¤	N12142 006	DEC 05, 1985
AP		200MG/VIAL¤	N12142 007	DEC 10, 1985
AP		500MG/VIAL¤	N12142 008	JAN 04, 1984
AP		1GM/VIAL¤	N12142 010	SEP 24, 1985
AP		2GM/VIAL¤	N12142 009	DEC 10, 1984

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-58)

SYRUP; ORAL
CYPROHEPTADINE HCL

AA	HALSEY DRUG	2MG/5ML¤	N89199 001	JUL 03, 1986

TABLET; ORAL
CYPROHEPTADINE HCL

AA	HALSEY DRUG	4MG¤	N89057 001	JUL 03, 1986

CYSTEINE HYDROCHLORIDE (PAGE 3-58)

INJECTABLE; INJECTION
CYSTEINE HCL

	KABIVITRUM	7.25%¤	N19523 001 OCT 22, 1986

DACARBAZINE (PAGE 3-58)

INJECTABLE; INJECTION

DACARBAZINE

AP	LYPHOMED	100MG/VIAL¤	N70962 001 AUG 28, 1986
AP		200MG/VIAL¤	N70990 001 AUG 28, 1986
AP	QUAD PHARMS	100MG/VIAL¤	N70821 001 OCT 09, 1986
AP		200MG/VIAL¤	N70822 001 OCT 09, 1986

DTIC-DOME

AP	MILES PHARMS/MILES	100MG/VIAL	N17575 001
AP		200MG/VIAL	N17575 002

DEXAMETHASONE (PAGE 3-60)

ELIXIR; ORAL

DEXAMETHASONE

AA	NASKA PHARMACAL	0.5MG/5ML¤	N88997 001 OCT 10, 1986

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-62)

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

AP	CARTER-GLOGAU LABS	EQ 4MG PHOSPHATE/ML¤	N89169 001 APR 09, 1986

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE (PAGE 3-63)

SOLUTION/DROPS; OPHTHALMIC

NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

AT	CARTER-GLOGAU LABS	EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML¤	N62714 001 JUL 21, 1986

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-62)

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

AT	CARTER-GLOGAU LABS	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML¤	N62721 001 NOV 17, 1986

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)

TABLET; ORAL

DEXCHLORPHENIRAMINE MALEATE

AA	SIDMAK LABORATORIES	2MG¤	N88682 001 JAN 17, 1986

POLARAMINE

AA	SCHERING	2MG	N86835 001

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION

DEXTROSE 5% IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	5GM/100ML¤	N19479 001 SEP 17, 1985
AP	TRAVENOL LABS	50MG/ML¤	N16673 003 OCT 30, 1985

DEXTROSE 50% IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	500MG/ML¤	N19445 001 JUN 03, 1986

DEXTROSE; DOPAMINE HYDROCHLORIDE (PAGE 3-65)

INJECTABLE; INJECTION

DOPAMINE HCL IN DEXTROSE 5%

	KENDALL MCGAW LABS	5GM/100ML;40MG/100ML¤	N19099 001 OCT 15, 1986
AP		5GM/100ML;80MG/100ML¤	N19099 002 OCT 15, 1986
AP		5GM/100ML;160MG/100ML¤	N19099 003 OCT 15, 1986
AP		5GM/100ML;320MG/100ML¤	190990 004 OCT 15, 1986

DOPAMINE HCL IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	5GM/100ML;320MG/100ML	N18826 003 SEP 30, 1983

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION

LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	5GM/100ML;200MG/100ML¤	N18954 001 JUL 09, 1985

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE; SODIUM LACTATE; SODIUM PHOSPHATE, MONOBASIC (PAGE 3-66)

INJECTABLE; INJECTION

IONOSOL B AND DEXTROSE 5% IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	5GM/100ML;53MG/100ML;100MG/100ML; 100MG/100ML;180MG/100ML; 280MG/100ML;16MG/100ML¤	N19515 001 MAY 08, 1986

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM LACTATE; SODIUM PHOSPHATE, MONOBASIC (PAGE 3-66)

INJECTABLE; INJECTION
IONOSOL MB AND DEXTROSE 5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5GM/100ML;30MG/100ML;141MG/100ML; 15MG/100ML;260MG/100ML; 25MG/100ML¤ N19513 001 MAY 08, 1986

DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM LACTATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, MONOBASIC (PAGE 3-66)

INJECTABLE; INJECTION
IONOSOL T AND DEXTROSE 5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5GM/100ML;111MG/100ML;256MG/100ML; 146MG/100ML;207MG/100ML¤ N19514 001 MAY 08, 1986

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE (PAGE 3-68)

INJECTABLE; INJECTION
DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5GM/100ML;74.5MG/100ML; 300MG/100ML¤ N18876 001 JAN 17, 1986

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5GM/100ML;149MG/100ML; 300MG/100ML¤ N18876 002 JAN 17, 1986

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.224% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5GM/100ML;224MG/100ML; 300MG/100ML¤ N18876 003 JAN 17, 1986

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER
AP KENDALL MCGAW LABS 5GM/100ML;75MG/100ML; 330MG/100ML¤ N18268 011 JAN 18, 1986

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER
AP KENDALL MCGAW LABS 5GM/100ML;150MG/100ML; 330MG/100ML¤ N18268 012 JAN 18, 1986

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE (PAGE 3-68)

INJECTABLE; INJECTION
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER
KENDALL MCGAW LABS 5GM/100ML;220MG/100ML; 330MG/100ML¤ N18268 013 JAN 18, 1986

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.30% IN PLASTIC CONTAINER
AP KENDALL MCGAW LABS 5GM/100ML;300MG/100ML; 330MG/100ML¤ N18268 014 JAN 18, 1986

DEXTROSE; SODIUM CHLORIDE (PAGE 3-70)

INJECTABLE; INJECTION
DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
AP ABBOTT LABORATORIES 5GM/100ML;225MG/100ML N17606 001
AP 5GM/100ML;225MG/100ML¤ N19482 001 OCT 04, 1985

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
AP ABBOTT LABORATORIES 5GM/100ML;300MG/100ML¤ N19486 001 OCT 04, 1985

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP ABBOTT LABORATORIES 5GM/100ML;450MG/100ML¤ N19484 001 OCT 04, 1985

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP ABBOTT LABORATORIES 5GM/100ML;900MG/100ML¤ N19483 001 OCT 04, 1985

DEXTROSE; THEOPHYLLINE (PAGE 3-70)

INJECTABLE; INJECTION
THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER
TRAVENOL LABS 5GM/100ML;320MG/100ML¤ N18649 006 NOV 13, 1985

DIAZEPAM (PAGE 3-72)

INJECTABLE; INJECTION
DIAZEPAM
AP CARTER-GLOGAU LABS 5MG/ML¤ N70296 001 FEB 12, 1986
AP ELKINS-SINN/AHROBINS 5MG/ML¤ N70311 001 DEC 16, 1985
AP 5MG/ML¤ N70312 001 DEC 16, 1985
AP 5MG/ML¤ N70313 001 DEC 16, 1985

DIAZEPAM (PAGE 3-72)

INJECTABLE; INJECTION

	DIAZEPAM			
AP	LEMMON	5MG/ML¤	N70911 001	AUG 28, 1986
AP		5MG/ML¤	N70912 001	AUG 28, 1986
>_ADD_> AP		5MG/ML¤	N70930 001	DEC 01, 1986
>_ADD_>				
AP	LYPHOMED	5MG/ML¤	N70662 001	JUN 25, 1986
	VALIUM			
AP	HOFFMANN-LA ROCHE	5MG/ML	N16087 001	

TABLET; ORAL

	DIAZEPAM			
AB	BARR LABORATORIES	2MG¤	N70152 001	NOV 01, 1985
AB		5MG¤	N70153 001	NOV 01, 1985
AB		10MG¤	N70154 001	NOV 01, 1985
AB	CHELSEA LABORATORIES	2MG¤	N70456 001	NOV 01, 1985
AB		5MG¤	N70457 001	NOV 01, 1985
AB		10MG¤	N70458 001	NOV 01, 1985
AB	CORD LABORATORIES	2MG¤	N70302 001	DEC 20, 1985
AB		5MG¤	N70303 001	DEC 20, 1985
AB		10MG¤	N70304 001	DEC 20, 1985
AB	DURAMED PHARMS	2MG¤	N70894 001	AUG 27, 1986
AB		5MG¤	N70895 001	AUG 27, 1986
AB		10MG¤	N70896 001	AUG 27, 1986
AB	HALSEY DRUG	2MG¤	N70987 001	AUG 15, 1986
AB		5MG¤	N70996 001	AUG 15, 1986
AB		10MG¤	N70956 001	AUG 15, 1986
AB	LEDERLE LABS/AM CYAN	2MG¤	N70226 001	SEP 26, 1985
AB		5MG¤	N70227 001	SEP 26, 1985
AB		10MG¤	N70228 001	SEP 26, 1985

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

	DIAZEPAM			
AB	MYLAN PHARMS	2MG¤	N70323 001	SEP 04, 1985
AB		5MG¤	N70324 001	SEP 04, 1985
AB		10MG¤	N70325 001	SEP 04, 1985
AB	PAR PHARMACEUTICAL	2MG¤	N70462 001	FEB 25, 1986
AB		5MG¤	N70463 001	FEB 25, 1986
AB		10MG¤	N70464 001	FEB 25, 1986
AB	PARKE-DAVIS/W-L	2MG¤	N70209 001	SEP 04, 1985
AB		5MG¤	N70210 001	SEP 04, 1985
AB		10MG¤	N70222 001	SEP 04, 1985
AB	PUREPAC/KALIPHARMA	2MG¤	N70781 001	MAR 19, 1986
AB		5MG¤	N70706 001	MAR 19, 1986
AB		10MG¤	N70707 001	MAR 19, 1986
AB	ROXANE LABORATORIES	2MG¤	N70356 001	JUN 17, 1986
AB		5MG¤	N70357 001	JUN 17, 1986
AB		10MG¤	N70358 001	JUN 17, 1986
AB	SUPERPHARM	2MG¤	N70642 001	DEC 11, 1985
AB		5MG¤	N70643 001	DEC 11, 1985
AB		10MG¤	N70644 001	DEC 11, 1985
AB	ZENITH LABORATORIES	2MG¤	N70360 001	SEP 04, 1985
>_ADD_> AB		2MG¤	N71307 001	DEC 10, 1986
>_ADD_>				
AB		5MG¤	N70361 001	SEP 04, 1985
>_ADD_> AB		5MG¤	N71321 001	DEC 10, 1986
>_ADD_>				
AB		10MG¤	N70362 001	SEP 04, 1985
>_ADD_> AB		10MG¤	N71322 001	DEC 10, 1986
>_ADD_>				

DIAZEPAM (PAGE 3-72)

TABLET; ORAL
Q-PAM
AB QUANTUM PHARMICS 2MG¤ N70423 001 DEC 12, 1985
AB 5MG¤ N70424 001 DEC 12, 1985
AB 10MG¤ N70425 001 DEC 12, 1985

VALIUM
AB HOFFMANN-LA ROCHE 2MG N13263 002
AB 5MG N13263 004
AB 10MG N13263 006

DICYCLOMINE HYDROCHLORIDE (PAGE 3-73)

CAPSULE; ORAL
BENTYL
AB MERRELL DOW/DOW CHEM 10MG N07409 001 OCT 15, 1984

DICYCLOMINE HCL
AB BOLAR PHARMACEUTICAL 10MG¤ N83179 001 FEB 12, 1986
AB CHELSEA LABORATORIES 10MG¤ N85082 001 JUN 19, 1986

INJECTABLE; INJECTION
BENTYL
AP MERRELL DOW/DOW CHEM 10MG/ML N08370 001 OCT 15, 1984

DICYCLOMINE HCL
AP CARTER-GLOGAU LABS 10MG/ML¤ N80614 001 FEB 11, 1986

TABLET; ORAL
BENTYL
AB MERRELL DOW/DOW CHEM 20MG N07409 001 OCT 15, 1984

DICYCLOMINE HCL
AB BARR LABORATORIES 20MG N84600 001 JUL 29, 1985
AB BOLAR PHARMACEUTICAL 20MG¤ N84361 001 FEB 06, 1986
AB PIONEER PHARMS 20MG¤ N88585 001 AUG 20, 1986

DIFLORASONE DIACETATE (PAGE 3-74)

CREAM; TOPICAL
DIFLORASONE DIACETATE
BX UPJOHN 0.05%¤ N19259 001 AUG 28, 1985

FLORONE
BX UPJOHN 0.05% N17741 001

DIFLORASONE DIACETATE (PAGE 3-74)

OINTMENT; TOPICAL
DIFLORASONE DIACETATE
BX UPJOHN 0.05%¤ N19260 001 AUG 28, 1985

FLORONE
BX UPJOHN 0.05% N17994 001

DILTIAZEM HYDROCHLORIDE (PAGE 3-75)

TABLET; ORAL
CARDIZEM
> ADD > MARION LABORATORIES 90MG¤ N18602 003 DEC 08, 1986
> ADD > 120MG¤ N18602 004 DEC 08, 1986

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-76)

CAPSULE; ORAL
DIPHENHYDRAMINE HCL
AA PIONEER PHARMS 25MG¤ N89101 001 DEC 20, 1985
AA 50MG¤ N88880 001 DEC 20, 1985

> ADD > DIPYRIDAMOLE (PAGE 3-77)

> ADD > TABLET; ORAL
> ADD > PERSANTINE
> ADD > BOEHRINGER INGELHEIM 25MG¤ N12836 003 DEC 22, 1986

DISOPYRAMIDE PHOSPHATE (PAGE 3-77)

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE
AB BARR LABORATORIES EQ 100MG BASE¤ N70351 001 DEC 17, 1985
AB EQ 150MG BASE¤ N70352 001 DEC 17, 1985
AB BOLAR PHARMACEUTICAL EQ 100MG BASE¤ N70240 001 FEB 02, 1986
AB EQ 150MG BASE¤ N70241 001 FEB 02, 1986

DISOPYRAMIDE PHOSPHATE (PAGE 3-77)

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

> ADD >	AB	CHELSEA LABORATORIES	EQ 100MG BASE¤	N71020 001	DEC 01, 1986
> ADD >					
> ADD >	AB		EQ 150MG BASE¤	N71021 001	DEC 01, 1986
> ADD >					
	AB	CORD LABORATORIES	EQ 100MG BASE¤	N70470 001	DEC 10, 1985
	AB		EQ 150MG BASE¤	N70471 001	DEC 10, 1985
	AB	ZENITH LABORATORIES	EQ 100MG BASE¤	N70186 001	NOV 18, 1985
	AB		EQ 150MG BASE¤	N70187 001	NOV 18, 1985

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION

DOPAMINE HCL

AP	ASTRA PHARM PRODS	40MG/ML¤	N70087 001	OCT 23, 1985
AP		80MG/ML¤	N70089 001	OCT 23, 1985
AP		80MG/ML¤	N70090 001	OCT 23, 1985
AP		80MG/ML¤	N70091 001	OCT 23, 1985
AP		160MG/ML¤	N70092 001	OCT 23, 1985
AP		160MG/ML¤	N70093 001	OCT 23, 1985
AP		160MG/ML¤	N70094 001	OCT 23, 1985
AP	LYPHOMED	160MG/ML¤	N70364 001	DEC 04, 1985
AP	SOLOPAK LABORATORIES	40MG/ML¤	N70011 001	AUG 29, 1985
AP		40MG/ML¤	N70046 001	AUG 29, 1985
AP		80MG/ML¤	N70047 001	AUG 29, 1985

DOPASTAT

AP	PARKE-DAVIS/W-L	40MG/ML¤	N70558 001	SEP 20, 1985
AP		80MG/ML¤	N70559 001	SEP 20, 1985

INTROPIN

AP	AM CRITICAL CARE/AHS	160MG/ML	N17395 003

DOXEPIN HYDROCHLORIDE (PAGE 3-78)

CAPSULE; ORAL

DOXEPIN HCL

AB	CHELSEA LABORATORIES	EQ 25MG BASE¤	N70953 001	MAY 15, 1986
AB		EQ 50MG BASE¤	N70954 001	MAY 15, 1986
AB		EQ 100MG BASE¤	N70955 001	MAY 15, 1986
AB	CORD LABORATORIES	EQ 25MG BASE¤	N70827 001	MAY 15, 1986
AB		EQ 50MG BASE¤	N70828 001	MAY 15, 1986
AB		EQ 75MG BASE¤	N70825 001	MAY 15, 1986
AB	MYLAN PHARMS	EQ 10MG BASE¤	N70789 001	MAY 13, 1986
AB		EQ 25MG BASE¤	N70790 001	MAY 13, 1986
AB		EQ 50MG BASE¤	N70791 001	MAY 13, 1986
AB		EQ 75MG BASE¤	N70792 001	MAY 13, 1986
AB		EQ 100MG BASE¤	N70793 001	MAY 13, 1986

DOXYCYCLINE HYCLATE (PAGE 3-79)

CAPSULE; ORAL

/DORYX/

/AB/	/FAULDING/	/EQ 100MG BASE/	/N50582 001/	/JUL 22, 1985/
/AB/	/PARKE-DAVIS/W-L/	/EQ 100MG BASE¤/	/N62653 001/	/OCT 30, 1985/

DOXYCYCLINE HYCLATE

AB	MUTUAL PHARM	EQ 50MG BASE¤	N62675 001	JUL 10, 1986
AB		EQ 100MG BASE¤	N62676 001	JUL 10, 1986
AB	PARKE-DAVIS/W-L	EQ 50MG BASE¤	N62594 001	DEC 05, 1985
AB		EQ 100MG BASE¤	N62594 002	DEC 05, 1985
AB	PRIVATE FORMULATIONS	EQ 50MG BASE¤	N62631 001	JUL 24, 1986
AB		EQ 100MG BASE¤	N62631 002	JUL 24, 1986

DOXYCYCLINE HYCLATE (PAGE 3-79)

CAPSULE, COATED PELLETS; ORAL

	DORYX			
AB	FAULDING	EQ 100MG BASE	N50582 001	JUL 22, 1985
AB	PARKE-DAVIS/W-L	EQ 100MG BASE¤	N62653 001	OCT 30, 1985

INJECTABLE; INJECTION

	DOXYCYCLINE			
/AB/	/MEDICOPHARMA/	/EQ 100MG BASE¤/	/N62538 001/	/APR 07, 1986/
	DOXYCYCLINE HYCLATE			
AP	QUAD PHARMS	EQ 100MG BASE/VIAL¤	N62643 001	FEB 13, 1986
AP		EQ 200MG BASE/VIAL¤	N62643 002	FEB 13, 1986

TABLET; ORAL

	DOXYCYCLINE HYCLATE			
AB	MEDICOPHARMA	EQ 100MG BASE¤	N62538 001	APR 07, 1986
AB	MUTUAL PHARM	EQ 100MG BASE¤	N62677 001	JUL 10, 1986
AB	PARKE-DAVIS/W-L	EQ 100MG BASE¤	N62593 001	AUG 28, 1985
/AB/		/EQ 50MG BASE¤/	/N62594 001/	/DEC 05, 1985/
/AB/		/EQ 100MG BASE¤/	/N62594 002/	/DEC 05, 1985/

DOXYLAMINE SUCCINATE (PAGE 3-80)

TABLET; ORAL

	DOXYLAMINE SUCCINATE			
AA	COPLEY PHARM	25MG¤	N88900 001	OCT 08, 1985

DROPERIDOL (PAGE 3-80)

INJECTABLE; INJECTION

	DROPERIDOL			
AP	LYPHOMED	2.5MG/ML¤	N70993 001	NOV 17, 1986
AP		2.5MG/ML¤	N70992 001	NOV 17, 1986
	INAPSINE			
AP	JANSSEN PHARMA	2.5MG/ML	N16796 001	

EDROPHONIUM CHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION

	ENLON			
AP	ANAQUEST/BOC	10MG/ML¤	N88873 001	AUG 06, 1985
	TENSILON			
AP	HOFFMANN-LA ROCHE	10MG/ML	N07959 001	

ENALAPRIL MALEATE (PAGE 3-81)

TABLET; ORAL

	VASOTEC			
	MS&D RES LABS/MERCK	5MG¤	N18998 001	DEC 24, 1985
		10MG¤	N18998 002	DEC 24, 1985
		20MG¤	N18998 003	DEC 24, 1985

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE (PAGE 3-81)

TABLET; ORAL

	VASERETIC			
	MS&D RES LABS/MERCK	10MG;25MG¤	N19221 001	OCT 31, 1986

> ADD > ENCAINIDE HYDROCHLORIDE (PAGE 3-81)

> ADD > CAPSULE; ORAL

> ADD >	ENKAID			
> ADD >	BRISTOL LABS/B-M	25MG¤	N18981 002	DEC 24, 1986
> ADD >		35MG¤	N18981 003	DEC 24, 1986
> ADD >		50MG¤	N18981 004	DEC 24, 1986

EPINEPHRINE (PAGE 3-81)

INJECTABLE; INJECTION

	SUS-PHRINE			
	/BERLEX/SCHERING/	/5MG/ML/	/N07942 001/	
	FOREST LABORATORIES	5MG/ML	N07942 001	

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION
LIDOCAINE HCL AND EPINEPHRINE

AP	ABBOTT LABORATORIES	0.005MG/ML;1.5%	N88571 001	SEP 13, 1985

XYLOCAINE W/ EPINEPHRINE

AP	ASTRA PHARM PRODS	0.005MG/ML;1.5%	N10418 010	
AP		0.005MG/ML;1.5%	N06488 017	AUG 29, 1986

ERGOLOID MESYLATES (PAGE 3-82)

TABLET; ORAL
ERGOLOID MESYLATES

AB	BARR LABORATORIES	1MG¤	N88891 001	NOV 01, 1985

TABLET; SUBLINGUAL
ERGOLOID MESYLATES

AA	SUPERPHARM	0.5MG¤	N89233 001	SEP 23, 1986
AA		1MG¤	N89234 001	SEP 23, 1986

ERYTHROMYCIN (PAGE 3-83)

CAPSULE, ENTERIC-COATED PELLETS; ORAL
ERYC

>ADD>	AB	PARKE-DAVIS/W-L	250MG¤	N62618 001	SEP 25, 1985

ERYC 125

		PARKE-DAVIS/W-L	125MG¤	N62648 001	OCT 24, 1985

ERYTHROMYCIN

>ADD>					
>ADD>	AB	ABBOTT LABORATORIES	250MG¤	N62746 001	DEC 22, 1986
>ADD>					

POWDER; FOR RX COMPOUNDING
ERYTHROMYCIN

	PADDOCK LABORATORIES	100%¤	N50610 001	NOV 07, 1986

ERYTHROMYCIN (PAGE 3-83)

~~TABLET, ENTERIC-COATED PARTICLES; ORAL~~
TABLET, COATED PARTICLES; ORAL
PCE

	ABBOTT LABORATORIES	333MG¤	N50611 001	SEP 09, 1986

ERYTHROMYCIN LACTOBIONATE (PAGE 3-85)

INJECTABLE; INJECTION
ERYTHROCIN LACTOBIONATE

AP	ABBOTT LABORATORIES	EQ 500MG BASE/VIAL¤	N50609 001	SEP 24, 1986
AP		EQ 1GM BASE/VIAL¤	N50609 002	SEP 24, 1986
AP		EQ 500MG BASE/VIAL¤	N62638 001	OCT 31, 1986
AP		EQ 1GM BASE/VIAL¤	N62638 002	OCT 31, 1986
AP	LYPHOMED	EQ 500MG BASE/VIAL¤	N62604 001	NOV 24, 1986
AP		EQ 1GM BASE/VIAL¤	N62604 002	NOV 24, 1986
AP	QUAD PHARMS	EQ 500MG BASE/VIAL¤	N62660 001	NOV 24, 1986
AP		EQ 1GM BASE/VIAL¤	N62660 003	NOV 24, 1986

>ADD> ESMOLOL HYROCHLORIDE (PAGE 3-86)

>ADD> INJECTABLE; INJECTION
>ADD> BREVIBLOC

>ADD>	DUPONT CRIT CRE	250MG/ML¤	N19386 001	DEC 31, 1986
>ADD>				

ESTRADIOL (PAGE 3-86)

FILM, CONTROLLED RELEASE; PERCUTANEOUS
ESTRADERM

	CIBA/CIBA-GEIGY	4MG¤	N19081 002	SEP 10, 1986
		8MG¤	N19081 003	SEP 10, 1986

ESTRADIOL CYPIONATE; TESTOSTERONE CYPIONATE (PAGE 3-86)

INJECTABLE; INJECTION
DEPO-TESTADIOL

AO	UPJOHN	2MG/ML;50MG/ML	N17968 001	

TESTOSTERONE CYPIONATE-ESTRADIOL CYPIONATE

AO	CARTER-GLOGAU LABS	2MG/ML;50MG/ML¤	N85603 001	MAR 13, 1986

ESTROGEN, CONJUGATED (PAGE 3-86)

TABLET; ORAL
CONJUGATED ESTROGENS

/BS/	/ICN PHARMACEUTICALS/	/0.3MG/	/N86492 001/	> ADD >
/BS/		/0.625MG/	/N83272 001/	> ADD >
/BS/		/1.25MG/	/N83294 001/	> ADD >
/BS/		/2.5MG/	/N83295 001/	> ADD >
BS	DURAMED PHARM	0.3MG	N86492 001	
BS		0.625MG	N83272 001	
BS		1.25MG	N83294 001	
BS		2.5MG	N83295 001	

ESTROGEN, CONJUGATED; MEPROBAMATE (PAGE 3-87)

TABLET; ORAL
PMB 200

/BS/	/AYERST LABS/AMHO/	/0.4MG;200MG/	/N10971 005/
BS	AYERST LABS/AMHO	0.45MG;200MG	N10971 005

PMB 400

/BS/	/AYERST LABS/AMHO/	/0.4MG;400MG/	/N10971 003/
BS	AYERST LABS/AMHO	0.45MG;400MG	N10971 003

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 3-89)

TABLET; ORAL-21
ORTHO-NOVUM 7/14-21

@	ORTHO PHARMACEUTICAL	0.035MG;0.5MG AND 1MG	N19004 001 APR 04, 1984

TABLET; ORAL-28
ORTHO-NOVUM 7/14-28

@	ORTHO PHARMACEUTICAL	0.35MG;0.5MG AND 1MG	N19004 002 APR 04, 1984

ETHINYL ESTRADIOL; NORETHINDRONE; FERROUS FUMARATE (PAGE 3-89)

TABLET; ORAL-28
NORQUEST FE

	SYNTEX (FP)	0.035MG;1MG;75MG	N18926 001 JUL 18, 1986

ETHOXZOLAMIDE (PAGE 3-90)

TABLET; ORAL
ETHAMIDE

@	ALLERGAN PHARMS	125MG	N16144 001

ETOPOSIDE (PAGE 3-91)

CAPSULE; ORAL
VEPESID

BRISTOL LABS/B-M	50MG¤	N19557 001 DEC 30, 1986
	100MG¤	N19557 002 DEC 30, 1986

ETRETINATE (PAGE 3-91)

CAPSULE; ORAL
TEGISON

HOFFMANN-LA ROCHE	10MG¤	N19369 001 SEP 30, 1986
	25MG¤	N19369 002 SEP 30, 1986

FAMOTIDINE (PAGE 3-91)

INJECTABLE; INJECTION
PEPCID

MSD RES LABS	10MG/ML¤	N19510 001 NOV 04, 1986

TABLET; ORAL
PEPCID

MSD RES LABS	20MG¤	N19462 001 OCT 15, 1986
	40MG¤	N19462 002 OCT 15, 1986

FLECAINIDE ACETATE (PAGE 3-92)

TABLET; ORAL
TAMBOCOR

RIKER LABS/3M	100MG¤	N18830 001 OCT 31, 1985
	200MG¤	N18830 002 OCT 31, 1985

FLUNISOLIDE (PAGE 3-92)

AEROSOL; INHALATION
/BRONALIDE/

/SYNTEX LABS/SYNTEX/	/0.025MG/INH/	/N18340 001/ /AUG 17, 1984/

AEROBID

KEY PHARMACEUTICALS	0.025MG/INH	N18340 001 AUG 17, 1984

FLUOCINOLONE ACETONIDE (PAGE 3-92)

SOLUTION; TOPICAL
FLUOCINOLONE ACETONIDE

AT	THAMES PHARMACAL	0.01%¤	N89124 001	SEP 11, 1985

FLUOROMETHOLONE (PAGE 3-93)

OINTMENT; OPHTHALMIC
FML

	ALLERGAN PHARMS	0.1%¤	N17760 001	SEP 04, 1985

SUSPENSION/DROPS; OPHTHALMIC
FLUOR-OP

AB	COOPERVISION PHARMS	0.1%¤	N70185 001	FEB 27, 1986

FML

AB	ALLERGAN PHARMS	0.1%	N16851 002	JUL 28, 1982

FML FORTE

	ALLERGAN PHARMS	0.25%¤	N19216 001	APR 23, 1986

FLUOROMETHOLONE ACETATE (PAGE 3-93)

SUSPENSION/DROPS; OPHTHALMIC
OMNITROL

	ALCON LABORATORIES	0.1%¤	N19079 001	FEB 11, 1986

FLUOROURACIL (PAGE 3-93)

INJECTABLE; INJECTION
FLUOROURACIL

AP	INTL PHARM PROD	50MG/ML¤	N88929 001	MAR 04, 1986
AP	LYPHOMED	50MG/ML¤	N89152 001	MAR 21, 1986

FLUPHENAZINE DECANOATE (PAGE 3-94)

INJECTABLE; INJECTION
FLUPHENAZINE

AO	QUAD PHARMS	25MG/ML¤	N70762 001	FEB 20, 1986

PROLIXIN DECANOATE

AO	ER SQUIBB AND SONS	25MG/ML	N16727 001	

FLUPHENAZINE HYDROCHLORIDE (PAGE 3-94)

CONCENTRATE; ORAL
PERMITIL

AA	SCHERING	5MG/ML	N16008 001	

PROLIXIN

AA	ER SQUIBB AND SONS	5MG/ML¤	N70533 001	NOV 07, 1985

FLURAZEPAM HYDROCHLORIDE (PAGE 3-95)

CAPSULE; ORAL
DALMANE

AB	ROCHE PRODUCTS	15MG	N16721 001	
AB		30MG	N16721 002	

FLURAZEPAM HCL

AB	BARR LABORATORIES	15MG¤	N70454 001	AUG 04, 1986
AB		30MG¤	N70455 001	AUG 04, 1986
AB	DANBURY PHARMACAL	15MG¤	N71205 001	NOV 25, 1986
AB		30MG¤	N71068 001	NOV 25, 1986
AB	MYLAN PHARMS	15MG¤	N70344 001	NOV 27, 1985
AB		30MG¤	N70345 001	NOV 27, 1985
AB	PAR PHARMACEUTICAL	15MG¤	N70444 001	MAR 20, 1986
AB		30MG¤	N70445 001	MAR 20, 1986
>ADD> AB	WEST-WARD	15MG¤	N71107 001	DEC 08, 1986
>ADD> AB		30MG¤	N71108 001	DEC 08, 1986

>ADD> FLURBIPROFEN (PAGE 3-95)

>ADD> SOLUTION/DROPS; OPHTHALMIC
>ADD> OCUFEN

>ADD>	ALLERGAN PHARMS	0.03%¤	N19404 001	DEC 31, 1986

/FOLATE SODIUM/(PAGE 3-95)

/INJECTABLE; INJECTION/
/FOLVITE/

/LEDERLE LABS/AM CYAN/5MG BASE/ML/			/N05897 008/	

FOLIC ACID (PAGE 3-95)

	INJECTABLE; INJECTION			
	FOLIC ACID			
AP	LYPHOMED	5MG/ML¤	N89202 001	FEB 18, 1986
	FOLVITE			
AP	LEDERLE LABS/AM CYAN	5MG/ML	N05897 008	
	TABLET; ORAL			
	FOLIC ACID			
AA	BARR LABORATORIES	1MG¤	N89177 001	JAN 08, 1986
AA	PIONEER PHARMS	1MG¤	N88949 001	SEP 13, 1985

FUROSEMIDE (PAGE 3-96)

	INJECTABLE; INJECTION			
	FUROSEMIDE			
AP	ASTRA PHARM PRODS	10MG/ML¤	N70014 001	SEP 09, 1985
AP		10MG/ML¤	N70095 001	SEP 09, 1985
AP		10MG/ML¤	N70096 001	SEP 09, 1985
AP	CARTER-GLOGAU LABS	10MG/ML¤	N70019 001	SEP 22, 1986
>ADD> AP	ORGANON/AKZONA	10MG/ML¤	N70017 001	DEC 15, 1986
>ADD> AP	SOLOPAK LABORATORIES	10MG/ML¤	N70023 001	FEB 05, 1986
AP		10MG/ML¤	N70078 001	FEB 05, 1986
	TABLET; ORAL			
	FUROSEMIDE			
AB	BARR LABORATORIES	20MG¤	N70043 001	SEP 26, 1985
AB	DANBURY PHARMACAL	20MG¤	N70412 001	FEB 26, 1986
AB		40MG¤	N70413 001	FEB 26, 1986
AB	MYLAN PHARMS	80MG¤	N70082 001	OCT 29, 1986
AB	ROXANE LABORATORIES	80MG¤	N70086 001	JAN 24, 1986
AB	WATSON LABORATORIES	20MG¤	N70449 001	NOV 22, 1985
AB		40MG¤	N70450 001	NOV 22, 1985
AB		80MG¤	N70528 001	JAN 07, 1986

GENTAMICIN SULFATE (PAGE 3-97)

	INJECTABLE; INJECTION			
	GENTAFAIR			
AP	PHARMAFAIR	EQ 40MG BASE/ML¤	N62493 001	AUG 28, 1985
	GENTAMICIN SULFATE			
AP	ABBOTT LABORATORIES	EQ 10MG BASE/ML¤	N62612 004	FEB 20, 1986
	SOLUTION/DROPS; OPHTHALMIC			
	GENTAMICIN SULFATE			
AT	CARTER-GLOGAU LABS	EQ 3MG BASE/ML¤	N62523 001	NOV 25, 1985

GENTAMICIN SULFATE; SODIUM CHLORIDE (PAGE 3-98)

	INJECTABLE; INJECTION			
	GENTAMICIN SULFATE IN PLASTIC CONTAINER			
AP	ABBOTT LABORATORIES	EQ 60MG BASE/100ML; 900MG/100ML¤	N62588 006	JAN 06, 1986
AP		EQ 70MG BASE/100ML; 900MG/100ML¤	N62588 007	JAN 06, 1986
AP		EQ 80MG BASE/100ML; 900MG/100ML¤	N62588 008	JAN 06, 1986
AP		EQ 90MG BASE/100ML; 900MG/100ML¤	N62588 009	JAN 06, 1986
AP		EQ 100MG BASE/100ML; 900MG/100ML¤	N62588 010	JAN 06, 1986
AP		EQ 1.2MG BASE/ML;9MG/ML¤	N62588 001	JAN 06, 1986
AP		EQ 1.4MG BASE/ML;9MG/ML¤	N62588 002	JAN 06, 1986
AP		EQ 1.6MG BASE/ML;9MG/ML¤	N62588 003	JAN 06, 1986
AP		EQ 1.8MG BASE/ML;9MG/ML¤	N62588 004	JAN 06, 1986
AP		EQ 2MG BASE/ML;9MG/ML¤	N62588 005	JAN 06, 1986

GLUTETHIMIDE (PAGE 3-100)

	TABLET; ORAL			
	GLUTETHIMIDE			
AA	HALSEY DRUG	250MG¤	N89458 001	OCT 10, 1986
AA		500MG¤	N89459 001	OCT 10, 1986

GLYCINE (PAGE 3-100)

SOLUTION; IRRIGATION

AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER

/AT/ /TRAVENOL LABS/ /1.5GM/100ML/ N18522 001/ /FEB/19,/1982/

GLYCINE 1.5% IN PLASTIC CONTAINER

AT	TRAVENOL LABS	1.5GM/100ML	N18522 001	FEB 19, 1982

GLYCOPYRROLATE (PAGE 3-100)

INJECTABLE; INJECTION

GLYCOPYRROLATE

AP	LUITPOLD PHARMS	0.2MG/ML¤	N89335 001	JUL 23, 1986
>ADD> AP	QUAD PHARMS	0.2MG/ML¤	N89397 001	DEC 09, 1986

GONADOTROPIN, CHORIONIC (PAGE 3-101)

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

>ADD> AP	QUAD PHARMS	5,000 UNITS/VIAL¤	N89312 001	DEC 04, 1986
>ADD> AP		5,000 UNITS/VIAL¤	N89313 001	DEC 04, 1986
>ADD> AP		10,000 UNITS/VIAL¤	N89314 001	DEC 04, 1986
>ADD> AP		10,000 UNITS/VIAL¤	N89315 001	DEC 04, 1986
>ADD> AP		20,000 UNITS/VIAL¤	N89316 001	DEC 04, 1986

GUANABENZ ACETATE (PAGE 3-102)

TABLET; ORAL

WYTENSIN

WYETH LABS/AMHO	EQ 16MG BASE¤	N18587 003	SEP 07, 1982

GUANFACINE HYDROCHLORIDE (PAGE 3-102)

TABLET; ORAL

TENEX

AH ROBINS	1MG¤	N19032 001	OCT 27, 1986

HALOPERIDOL (PAGE 3-102)

TABLET; ORAL

HALDOL

AB	MCNEIL PHARM	0.5MG	N15921 001
AB		1MG	N15921 002
AB		2MG	N15921 003
AB		5MG	N15921 004
AB		10MG	N15921 005
AB		20MG	N15921 006 FEB 02, 1982

HALOPERIDOL

AB	CORD LABORATORIES	0.5MG¤	N71206 001 NOV 17, 1986
AB		1MG¤	N71207 001 NOV 17, 1986
AB		2MG¤	N71208 001 NOV 17, 1986
AB		5MG¤	N71209 001 NOV 17, 1986
>ADD> AB	DURAMED PHARMS	0.5MG¤	N71216 001 DEC 04, 1986
>ADD> AB		1MG¤	N71217 001 DEC 04, 1986
>ADD> AB		2MG¤	N71218 001 DEC 04, 1986
>ADD> AB		5MG¤	N71219 001 DEC 04, 1986
AB	MYLAN PHARMS	0.5MG¤	N70276 001 JUN 10, 1986
AB		1MG¤	N70277 001 JUN 10, 1986
AB		2MG¤	N70278 001 JUN 10, 1986
AB		5MG¤	N70279 001 JUN 10, 1986
AB	PAR PHARMACEUTICAL	0.5MG¤	N71233 001 NOV 03, 1986
AB		1MG¤	N71234 001 NOV 03, 1986
AB		2MG¤	N71235 001 NOV 03, 1986
AB		5MG¤	N71236 001 NOV 03, 1986
AB	PUREPAC/KALIPHARMA	0.5MG¤	N71071 001 NOV 03, 1986
AB		1MG¤	N71072 001 NOV 03, 1986
AB		2MG¤	N71073 001 NOV 03, 1986
AB		5MG¤	N71074 001 NOV 03, 1986

HALOPERIDOL (PAGE 3-102)

TABLET; ORAL

	HALOPERIDOL		
AB	SEARLE PHARMS	0.5MG¤	N70720 001
			JUN 10, 1986
AB		1MG¤	N70721 001
			JUN 10, 1986
AB		2MG¤	N70722 001
			JUN 10, 1986
AB		5MG¤	N70723 001
			JUN 10, 1986
AB		10MG¤	N70724 001
			JUN 10, 1986
AB		20MG¤	N70725 001
		SEP 24, 1986 :	JUN 10, 1986

HALOPERIDOL DECANOATE (PAGE 3-102)

INJECTABLE; INJECTION

	HALDOL DECANOATE		
	MCNEIL PHARM	EQ 50MG BASE/ML¤	N18701 001
			JAN 14, 1986

HALOPERIDOL LACTATE (PAGE 3-102)

CONCENTRATE; ORAL

	HALDOL		
AA	MCNEIL LABORATORIES	EQ 2MG BASE/ML	N15922 001
	HALOPERIDOL		
AA	BAY LABORATORIES	EQ 2MG BASE/ML¤	N70710 001
		APR 15, 1986 :	MAR 07, 1986
AA	NATL PHARM MFG/BARRE	EQ 2MG BASE/ML¤	N70318 001
		APR 15, 1986 :	APR 11, 1986
AA	SEARLE PHARMS	EQ 2MG BASE/ML¤	N70726 001
			JUN 10, 1986

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION

	HEP-LOCK PF		
/AP/	/ELKINS-SINN/AHROBINS/	/10 UNITS/ML/	/N17037 010/
			/JUN 10, 1983/
/AP/		/100 UNITS/ML/	/N17037 011/
			/JUN 10, 1983/
	HEP-LOCK U/P		
AP	ELKINS-SINN/AHROBINS	10 UNITS/ML	N17037 010
			JUN 10, 1983
AP		100 UNITS/ML	N17037 011
			JUN 10, 1983

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION

	HEPARIN LOCK FLUSH		
AP	CARTER-GLOGAU LABS	100 UNITS/ML	N17064 001
AP	LUITPOLD PHARMS	10 UNITS/ML¤	N89063 001
			OCT 09, 1985
AP		100 UNITS/ML¤	N89064 001
			OCT 09, 1985
	HEPARIN SODIUM		
AP	ABBOTT LABORATORIES	2,000 UNITS/ML¤	N05264 013
			APR 07, 1986
AP		2,500 UNITS/ML¤	N05264 014
			APR 07, 1986
/AP/	CARTER-GLOGAU LABS	/100 UNIT/ML/	/N17064 001/
AP		2,500 UNITS/ML	N17064 015
AP		7,500 UNITS/ML	N17064 019
		3,000 UNITS/ML	N17064 016
		4,000 UNITS/ML	N17064 017
		6,000 UNTIS/ML	N17064 018
AP	ELKINS-SINN/AHROBINS	5,000 UNITS/0.5ML¤	N17037 013
			APR 07, 1986
	HEPARIN SODIUM PRESERVATIVE FREE		
AP	INVENEX/LYPHOMED	1,000 UNITS/ML¤	N17029 010
			APR 28, 1986
AP	MARSAM	1,000 UNITS/ML¤	N89464 001
			JUN 03, 1986
	LIQUAEMIN SODIUM PRESERVATIVE FREE		
AP	ORGANON/AKZONA	1,000 UNITS/ML¤	N00552 011
			APR 11, 1986
AP		5,000 UNITS/ML¤	N00552 012
			APR 11, 1986
AP		10,000 UNITS/ML¤	N00552 013
			APR 11, 1986
	SODIUM HEPARIN		
/AP/	/CARTER-GLOGAU LABS/	/2,500 UNITS/ML/	/N17064 015/
/AP/		/7,500 UNITS/ML/	/N17064 019/
		/3,000 UNITS/ML/	/N17064 016/
		/4,000 UNITS/ML/	/N17064 017/
		/6,000 UNITS/ML/	/N17064 018/

HEXACHLOROPHENE (PAGE 3-106)

SPONGE; TOPICAL

	/E-Z SCRUB SURGICAL/		
	/PARKE-DAVIS/W-L/	/450MG/	/N17452 001/
	E-Z SCRUB		
	DESERET/P-D	450MG	N17452 001

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

	INJECTABLE; INJECTION			
	HYDRALAZINE HCL			
AP	SOLOPAK LABORATORIES	20MG/ML¤	N88517 001	AUG 22, 1985
	TABLET; ORAL			
	HYDRALAZINE HCL			
AA	HALSEY DRUG	10MG¤	N89218 001	JAN 22, 1986
AA		25MG¤	N89130 001	JAN 15, 1986
AA		50MG¤	N89222 001	JAN 22, 1986
AA		100MG¤	N89178 001	JAN 15, 1986
AA	MUTUAL PHARM	10MG¤	N89359 001	JUL 25, 1986
AA		25MG¤	N89258 001	MAY 05, 1986
AA		50MG¤	N89259 001	MAY 05, 1986
AA	SIDMAK LABORATORIES	10MG¤	N89097 001	DEC 18, 1985
AA		100MG¤	N89098 001	DEC 18, 1985

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-108)

	CAPSULE; ORAL			
	HYDRA-ZIDE			
AB	PAR PHARMACEUTICAL	25MG;25MG¤	N88957 001	OCT 21, 1985
AB		50MG;50MG¤	N88946 001	OCT 21, 1985
AB		100MG;50MG¤	N88961 001	OCT 21, 1985

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)

	TABLET; ORAL			
	ALDORIL D30			
AB	MS&D/MERCK	30MG;500MG	N13402 003	
	ALDORIL D50			
AB	MS&D/MERCK	50MG;500MG	N13402 004	
	ALDORIL 15			
AB	MS&D/MERCK	15MG;250MG	N13402 001	
	ALDORIL 25			
AB	MS&D/MERCK	25MG;250MG	N13402 002	

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)

	TABLET; ORAL			
	METHYLDOPA AND HYDROCHLOROTHIAZIDE			
AB	BOLAR PHARMACEUTICAL	15MG;250MG¤	N70365 001	MAR 19, 1986
AB		25MG;250MG¤	N70366 001	APR 16, 1986
AB		30MG;500MG¤	N70367 001	MAR 19, 1986
AB		50MG;500MG¤	N70368 001	APR 16, 1986
AB	CORD LABORATORIES	15MG;250MG¤	N70182 001	JAN 15, 1986
AB		25MG;250MG¤	N70183 001	JAN 15, 1986
AB		30MG;500MG¤	N70543 001	JAN 15, 1986
AB		50MG;500MG¤	N70544 001	JAN 15, 1986
AB	MYLAN PHARMS	15MG;250MG¤	N70264 001	JAN 23, 1986
AB		25MG;250MG¤	N70265 001	JAN 23, 1986
AB	PUREPAC/KALIPHARMA	15MG;250MG¤	N70853 001	OCT 08, 1986
AB		25MG;250MG¤	N70688 001	APR 24, 1986
AB		30MG;500MG¤	N70854 001	OCT 08, 1986
AB		50MG;500MG¤	N70689 001	APR 24, 1986

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE (PAGE 3-111)

	TABLET; ORAL			
	INDERIDE-40/25			
AB	AYERST LABS/AMHO	25MG;40MG	N18031 001	
	INDERIDE-80/25			
AB	AYERST LABS/AMHO	25MG;80MG	N18031 002	
	PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE			
AB	BARR LABORATORIES	25MG;40MG¤	N70704 001	OCT 01, 1986
AB		25MG;80MG¤	N70705 001	OCT 01, 1986
AB	CHELSEA LABORATORIES	25MG;40MG¤	N70301 001	APR 18, 1986
AB		25MG;80MG¤	N70305 001	APR 18, 1986
AB	PUREPAC/KALIPHARMA	25MG;40MG¤	N70851 001	MAY 15, 1986
AB		25MG;80MG¤	N70852 001	MAY 15, 1986

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

AB	PUREPAC/KALIPHARMA	25MG;25MG¤	N87999 001	NOV 06, 1985
AB	SUPERPHARM	25MG;25MG¤	N89137 001	AUG 26, 1985

/HYDROCODONE; PHENYLTOLOXAMINE/(PAGE 3-112)

/SUSPENSION; ORAL/
/TUSSIONEX/

	/PENNWALT PHARM/	/EQ 5MG BASE/5ML;/ /EQ 10MG BASE/5ML/	/N16768 006/	

HYDROCORTISONE (PAGE 3-112)

CREAM; TOPICAL
ALA-CORT

AT	DEL-RAY LABORATORIES	1%	N80706 001	

HYDROCORTISONE

> ADD > AT	E FOUGERA/ALTANA	2.5%¤	N89414 001	DEC 16, 1986
> ADD > AT	PHARMADERM/ALTANA	1%¤	N88845 001	FEB 27, 1986
> ADD > AT		2.5%¤	N89413 001	DEC 16, 1986

LOTION; TOPICAL
ALA-CORT

AT	DEL-RAY LABORATORIES	1%	N83201 001	

ALA-SCALP

	DEL-RAY LABORATORIES	2%	N83231 001	

HYDROCORTISONE

AT	THAMES PHARMACAL	1%¤	N89024 001	FEB 12, 1986

STIE-CORT

AT	STIEFEL LABORATORIES	1%¤	N89066 001	NOV 25, 1985
AT		2.5%¤	N89074 001	NOV 26, 1985

OINTMENT; TOPICAL
HYDROCORTISONE IN ABSORBASE

AT	CAROLINA MED PRODS	1%¤	N88138 001	SEP 06, 1985

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-115)

SUSPENSION; OTIC
NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT	CARTER-GLOGAU LABS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML¤	N62488 001	NOV 06, 1985

NEOMYCIN SULFATE, POLYMYXIN B SULFATE & HYDROCORTISONE

AT	PHARMAFAIR	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML¤	N62617 001	SEP 18, 1985

SUSPENSION/DROPS; OPHTHALMIC
CORTISPORIN

AT	BURROUGHS WELLCOME	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N50169 001	

NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE

AT	PHARMAFAIR	1%:EQ 3.5MG BASE/ML; 10,000 UNITS/ML¤	N62623 001	SEP 24, 1985

HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-116)

CREAM; TOPICAL
CORTISPORIN

	BURROUGHS WELLCOME	0.5%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM¤	N50218 001	AUG 09, 1985

HYDROCORTISONE BUTYRATE (PAGE 3-116)

CREAM; TOPICAL
HYDROCORTISONE BUTYRATE

BX	∂ GIST-BROCADES	0.1%	N18514 001	MAY 31, 1982

LOCOID

BX	OWEN LABS/DERM PRODS	0.1%	N18795 001	JAN 07, 1983

OINTMENT; TOPICAL
HYDROCORTISONE BUTYRATE

BX	∂ GIST-BROCADES	0.1%	N18652 001	OCT 29, 1982

LOCOID

BX	OWEN LABS/DERM PRODS	0.1%	N19106 001	JUL 03, 1984

HYDROFLUMETHIAZIDE; RESERPINE (PAGE 3-117)

TABLET; ORAL
HYDROFLUMETHIAZIDE AND RESERPINE

BP	PAR PHARMACEUTICAL	50MG;0.125MG¤	N88907 001 SEP 20, 1985

HYDROXYZINE HYDROCHLORIDE (PAGE 3-118)

INJECTABLE; INJECTION
HYDROXYZINE

AP	ELKINS-SINN/AHROBINS	50MG/ML	N85551 002

HYDROXYZINE HCL

/AP/	/ELKINS-SINN/AHROBINS/	50MG/ML/	/N85551 002/
AP	PHARMAFAIR	25MG/ML¤	N88862 001 FEB 14, 1986
AP		25MG/ML¤	N89106 001 FEB 14, 1986
AP		50MG/ML¤	N88881 001 FEB 14, 1986
AP		50MG/ML¤	N89107 001 FEB 14, 1986

TABLET; ORAL
HYDROXYZINE HCL

AB	AMIDE PHARMACEUTICAL	10MG¤	N89071 001 JUL 22, 1986
AB		25MG¤	N89072 001 JUL 22, 1986
AB		50MG¤	N89073 001 JUL 22, 1986
AB	COLMED LABORATORIES	10MG¤	N89121 001 MAR 20, 1986
AB		25MG¤	N89122 001 MAR 20, 1986
AB		50MG¤	N89123 001 MAR 20, 1986
AB	MUTUAL PHARM	10MG¤	N89381 001 MAY 19, 1986
AB		25MG¤	N89382 001 MAY 19, 1986
AB		50MG¤	N89383 001 MAY 19, 1986
AB	QUANTUM PHARMICS	10MG¤	N88540 001 OCT 22, 1985
AB		25MG¤	N88551 001 OCT 22, 1985
AB		50MG¤	N88529 001 OCT 22, 1985
AB	SIDMAK LABORATORIES	10MG¤	N88617 001 JAN 10, 1986
AB		25MG¤	N88618 001 JAN 10, 1986
AB		50MG¤	N88619 001 JAN 10, 1986

HYDROXYZINE PAMOATE (PAGE 3-120)

CAPSULE; ORAL
HYDROXYZINE PAMOATE

AB	PAR PHARMACEUTICAL	EQ 25MG HCL¤	N89145 001 MAR 17, 1986
AB		EQ 50MG HCL¤	N89146 001 MAR 17, 1986

IBUPROFEN (PAGE 3-120)

TABLET; ORAL
IBUPROFEN

AB	BOOTS PHARMACEUTICAL	800MG¤	N71264 001 JUL 25, 1986
> ADD > AB	CHELSEA LABORATORIES	300MG¤	N71338 001 DEC 01, 1986
> ADD > AB		400MG¤	N70038 001 SEP 06, 1985
AB		600MG¤	N70041 001 SEP 06, 1985
AB	CORD LABORATORIES	300MG¤	N70734 001 JUN 12, 1986
AB		400MG¤	N70735 001 JUN 12, 1986
AB		600MG¤	N70736 001 JUN 12, 1986
AB	DANBURY PHARMACAL	400MG¤	N70436 001 AUG 21, 1985
AB		600MG¤	N70437 001 AUG 21, 1985
AB	INTERPHARM	400MG¤	N71334 001 NOV 25, 1986
AB		600MG¤	N71335 001 NOV 25, 1986
AB	LEDERLE LABS/AM CYAN	400MG¤	N70629 001 SEP 19, 1986
AB		600MG¤	N70630 001 SEP 19, 1986
AB	MCNEIL CONSUMER PROD	400MG¤	N70081 001 JUN 16, 1986
AB		600MG¤	N70476 001 JUN 16, 1986
AB	MUTUAL PHARM	300MG¤	N71230 001 OCT 22, 1986
AB		400MG¤	N71231 001 OCT 22, 1986
AB		600MG¤	N71232 001 OCT 22, 1986
AB	MYLAN PHARMS	400MG¤	N70045 001 SEP 24, 1985
AB		600MG¤	N70057 001 SEP 24, 1985

IBUPROFEN (PAGE 3-120)

TABLET; ORAL

	IBUPROFEN			
AB	OHM LABORATORIES	400MG¤	N70818 001	DEC 26, 1985
AB	/℞/PAR PHARMACEUTICAL	300MG¤	N70328 001	AUG 06, 1985
AB		400MG¤	N70329 001	AUG 06, 1985
AB		600MG¤	N70330 001	AUG 06, 1985
AB		800MG¤	N70986 001	JUL 25, 1986
AB	PRIVATE FORMULATIONS	300MG¤	N71266 001	OCT 15, 1986
AB		400MG¤	N71267 001	OCT 15, 1986
AB		600MG¤	N71268 001	OCT 15, 1986
AB	PUREPAC/KALIPHARMA	300MG¤	N71123 001	SEP 19, 1986
AB		400MG¤	N71124 001	SEP 19, 1986
AB		600MG¤	N71125 001	SEP 19, 1986
AB	SUPERPHARM	400MG¤	N70708 001	APR 25, 1986
AB		600MG¤	N70709 001	APR 25, 1986
	IBUPROHM			
AB	OHM LABORATORIES	400MG¤	N70469 001	AUG 29, 1985
	IFEN			
AB	LUCHEM PHARMS	400MG¤	N71145 001	SEP 23, 1986
AB		600MG¤	N71146 001	SEP 23, 1986
	MOTRIN			
AB	/℞/UPJOHN	300MG	N17463 003	MAY 22, 1985
AB		800MG¤	N17463 005	
	RUFEN			
AB	BOOT PHARMACEUTICAL	800MG¤	N70745 001	JUL 23, 1986

INDIUM IN-111 OXYQUINOLINE (PAGE 3-121)

INJECTABLE; INJECTION

	INDIUM IN-111 OXYQUINOLINE			
	AMERSHAM/RADIOCHEM	N/A¤	N19044 001	DEC 23, 1985

INDOMETHACIN (PAGE 3-122)

CAPSULE; ORAL

	INDO-LEMMON			
AB	LEMMON	25MG¤	N70266 001	NOV 07, 1985
AB		50MG¤	N70267 001	NOV 07, 1985
	INDOMETHACIN			
AB	BARR LABORATORIES	25MG¤	N70067 001	OCT 03, 1986
AB		50MG¤	N70068 001	OCT 03, 1986
AB	BOLAR PHARMACEUTICAL	25MG¤	N70784 001	AUG 20, 1986
AB		50MG¤	N70785 001	AUG 20, 1986
AB	DURAMED PHARMS	25MG¤	N70326 001	OCT 18, 1985
AB		50MG¤	N70327 001	OCT 18, 1985
AB	MYLAN PHARMS	50MG¤	N70624 001	SEP 04, 1985
AB	PAR PHARMACEUTICAL	50MG¤	N70651 001	MAR 05, 1986
AB	PIONEER PHARMS	25MG¤	N70813 001	AUG 11, 1986
AB		50MG¤	N70592 001	AUG 11, 1986
AB	SUPERPHARM	25MG¤	N70487 001	OCT 10, 1986
AB		50MG¤	N70488 001	OCT 10, 1986
AB	WATSON LABORATORIES	25MG¤	N70529 001	OCT 18, 1985
AB		50MG¤	N70530 001	OCT 18, 1985
AB	ZENITH LABORATORIES	25MG¤	N70719 001	FEB 12, 1986
AB		50MG¤	N70756 001	FEB 12, 1986

SUSPENSION; ORAL

	INDOCIN			
	MS&D RES LABS/MERCK	25MG/5ML¤	N18332 001	OCT 10, 1985

IOHEXOL (PAGE 3-123)

INJECTABLE; INJECTION

	OMNIPAQUE 180			
	WINTHROP-BREON/STERL	38.8%¤	N18956 001	DEC 26, 1985

IOHEXOL (PAGE 3-123)

INJECTABLE; INJECTION
OMNIPAQUE 240
WINTHROP-BREON/STERL 51.8%¤ N18956 002 DEC 26, 1985

OMNIPAQUE 300
WINTHROP-BREON/STERL 64.7%¤ N18956 003 DEC 26, 1985

OMNIPAQUE 350
WINTHROP-BREON/STERL 75.5%¤ N18956 004 DEC 26, 1985

IOPAMIDOL (PAGE 3-123)

INJECTABLE; INJECTION
ISOVUE-300
ER SQUIBB AND SONS 61%¤ N18735 002 DEC 31, 1985

ISOVUE-370
ER SQUIBB AND SONS 76%¤ N18735 003 DEC 31, 1985

ISOVUE-M 200
ER SQUIBB AND SONS 41%¤ N18735 001 DEC 31, 1985

ISOVUE-M 300
ER SQUIBB AND SONS 61%¤ N18735 004 DEC 31, 1985

> ADD > IPRATROPIUM BROMIDE (PAGE 3-124)

> ADD > AEROSOL; INHALATION
> ADD > ATROVENT
> ADD > BOEHRINGER INGELHEIM 0.018MG/INH¤ N19085 001 DEC 29, 1986
> ADD >

ISOETHARINE HYDROCHLORIDE (PAGE 3-124)

SOLUTION; INHALATION
ISOETHARINE HCL S/F
AN DEY LABORATORIES 1%¤ N89252 001 SEP 15, 1986

ISONIAZID (PAGE 3-125)

SYRUP; ORAL
LANIAZID
AA LANNETT 50MG/5ML¤ N89243 001 FEB 03, 1986

ISOSORBIDE DINITRATE (PAGE 3-126)

TABLET; ORAL
ISOSORBIDE DINITRATE
BARR LABORATORIES 5MG¤ N86166 001 SEP 19, 1986
10MG¤ N86169 001 SEP 19, 1986
20MG¤ N86167 001 SEP 19, 1986
30MG¤ N87564 001 SEP 18, 1986

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE
BARR LABORATORIES 2.5MG¤ N84204 001 SEP 18, 1986
5MG¤ N86168 001 SEP 18, 1986
10MG¤ N87545 001 SEP 18, 1986

KANAMYCIN SULFATE (PAGE 3-126)

INJECTABLE; INJECTION
KANAMYCIN SULFATE
AP QUAD PHARMS EQ 75MG BASE/2ML¤ N62642 001 FEB 03, 1986
AP EQ 500MG BASE/2ML¤ N62642 002 FEB 03, 1986
AP EQ 1GM BASE/3ML¤ N62642 003 FEB 03, 1986
AP SOLOPAK LABORATORIES EQ 75MG BASE/2ML¤ N62605 003 FEB 26, 1986
AP EQ 500MG BASE/2ML¤ N62605 001 FEB 26, 1986
AP EQ 1GM BASE/3ML¤ N62605 002 FEB 26, 1986

KETOCONAZOLE (PAGE 3-127)

CREAM; TOPICAL
NIZORAL
JANSSEN PHARMA 2%¤ N19084 001 DEC 31, 1985

SUSPENSION; ORAL
NIZORAL
JANSSEN PHARM 100MG/5ML¤ N70767 001 NOV 07, 1986

KETOPROFEN (PAGE 3-127)

CAPSULE; ORAL
ORUDIS

	WYETH LABS/AMHO	50MG¤	N18754 002	JAN 09, 1986
		75MG¤	N18754 003	JAN 09, 1986

LABETALOL HYDROCHLORIDE (PAGE 3-127)

INJECTABLE; INJECTION
NORMODYNE

AP	SCHERING	5MG/ML	N18686 001	AUG 01, 1984

TRANDATE

AP	GLAXO	5MG/ML¤	N19425 001	DEC 31, 1985

LACTULOSE (PAGE 3-127)

SYRUP; ORAL
LACTULOSE

AA	ROXANE LABORATORIES	10GM/15ML	N17906 001	

LEUCOVORIN CALCIUM (PAGE 3-127)

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

>ADD > AP	LEDERLE LABS/AM CYAN	EQ 50MG BASE/VIAL	N08107 002	
>ADD > AP >ADD >	LYPHOMED	EQ 50MG BASE/VIAL¤	N88939 001	DEC 01, 1986

TABLET; ORAL
LEUCOVORIN CALCIUM

BX	LEDERLE LABS/AM CYAN	EQ 5MG BASE¤	N18459 001	JAN 30, 1986

WELLCOVORIN

BX	BURROUGHS WELLCOME	EQ 5MG BASE	N18342 001	JUL 08, 1983

LEVOBUNOLOL HYDROCHLORIDE (PAGE 3-128)

SOLUTION/DROPS; OPHTHALMIC
BETAGAN

	ALLERGAN PHARMS	0.5%¤	N19219 002	DEC 19, 1985

LITHIUM CITRATE (PAGE 3-132)

SYRUP; ORAL
LITHIUM CITRATE

AA	MY-K LABS	EQ 300MG CARBONATE/5ML	N70755 001	MAY 21, 1986

LORAZEPAM (PAGE 3-132)

TABLET; ORAL
ATIVAN

AB	WYETH LABS/AMHO	0.5MG	N17794 001	
AB		1MG	N17794 002	
AB		2MG	N17794 003	

LORAZEPAM

AB	AM THERAPEUTIC	0.5MG¤	N70727 001	MAR 07, 1986
AB		1MG¤	N70728 001	MAR 07, 1986
AB		2MG¤	N70729 001	MAR 07, 1986

LORAZEPAM

AB	BARR LABORATORIES	0.5MG¤	N70472 001	DEC 10, 1985
AB		1MG¤	N70473 001	DEC 10, 1985
AB		2MG¤	N70474 001	DEC 10, 1985
>ADD > AB >ADD >	COLMED LABORATORIES	1MG¤	N70539 001	DEC 22, 1986
>ADD > AB >ADD >		2MG¤	N70540 001	DEC 22, 1986
AB	DANBURY PHARMACAL	0.5MG¤	N71117 001	JUL 24, 1986
AB		1MG¤	N71118 001	JUL 24, 1986
AB		2MG¤	N71110 001	JUL 24, 1986
>ADD > AB >ADD >	PAR PHARMACEUTICAL	0.5MG¤	N70675 001	DEC 01, 1986
>ADD > AB >ADD >		1MG¤	N70676 001	DEC 01, 1986
>ADD > AB >ADD >		2MG¤	N70677 001	DEC 01, 1986
AB	QUANTUM PHARMICS	0.5MG¤	N70200 001	AUG 09, 1985
AB		1MG¤	N70201 001	AUG 09, 1985
AB		2MG¤	N70202 001	AUG 09, 1985

LOXAPINE SUCCINATE (PAGE 3-132)

TABLET; ORAL
LOXITANE
ə LEDERLE LABS/AM CYAN EQ 10MG BASE N17525 006
ə EQ 25MG BASE N17525 007
ə EQ 50MG BASE N17525 008

MAGNESIUM SULFATE (PAGE 3-134)

INJECTABLE; INJECTION
MAGNESIUM SULFATE
LYPHOMED 500MG/ML¤ N19316 001
SEP 08, 1986

MANGANESE CHLORIDE (PAGE 3-134)

INJECTABLE; INJECTION
MANGANESE CHLORIDE IN PLASTIC CONTAINER
ABBOTT LABORATORIES EQ 0.1MG MANGANESE/ML¤ N18962 001
JUN 26, 1986

MANNITOL (PAGE 3-134)

SOLUTION; IRRIGATION
RESECTISOL
/AM MCGAW/AM HOSP/ /5GM/100ML/ /N16772/002/
RESECTISOL IN PLASTIC CONTAINER
AM MCGAW/AM HOSP 5GM/100ML N16772 002

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

TABLET; ORAL
MECLIZINE HCL
AA SIDMAK LABORATORIES 12.5MG¤ N88732 001
DEC 11, 1985
AA 25MG¤ N88734 001
DEC 11, 1985
AA SUPERPHARM 12.5MG¤ N89113 001
AUG 20, 1985
AA 25MG¤ N89114 001
AUG 20, 1985

TABLET, CHEWABLE; ORAL
MECLIZINE HCL
AA SIDMAK LABORATORIES 25MG¤ N88733 001
DEC 11, 1985

MECLOFENAMATE SODIUM (PAGE 3-136)

CAPSULE; ORAL
MECLOFENAMATE SODIUM
AB BOLAR PHARMACEUTICAL EQ 50MG BASE¤ N70400 001
NOV 25, 1986
AB EQ 100MG BASE¤ N70401 001
NOV 25, 1986
AB MYLAN PHARMS EQ 50MG BASE¤ N71080 001
SEP 03, 1986
AB EQ 100MG BASE¤ N71081 001
SEP 03, 1986
MECLOMEN
AB PARKE-DAVIS/W-L EQ 50MG BASE N18006 001
AB EQ 100MG BASE N18006 002

MEDROXYPROGESTERONE ACETATE (PAGE 3-136)

TABLET; ORAL
PROVERA
UPJOHN 5MG N11839 003

MENOTROPINS (PAGE 1-137)

INJECTABLE; INJECTION
PERGONAL
/SERONO LABS/ /150 IU/AMP/ /N17646 001/
/300 IU/AMP/ /N17646 002/
SERONO LABS 75 IU/AMP N17646 001
150 IU/AMP N17646 002
MAY 20, 1985

> ADD > MEPHENYTOIN (PAGE 3-138)

> ADD > TABLET; ORAL
> ADD > MESANTOIN
> ADD > SANDOZ PHARMS/SANDOZ 100MG N06008 001

MEPIVACAINE HYDROCHLORIDE (PAGE 3-138)

INJECTABLE; INJECTION
CARBOCAINE
> ADD > AP WINTHROP-BREON/STERL 1.5% N12250 005
POLOCAINE
> ADD > AP ASTRA PHARM PRODS 1%¤ N89406 001
> ADD > DEC 01, 1986
> ADD > AP 1%¤ N89407 001
> ADD > DEC 01, 1986
> ADD > AP 1.5%¤ N89408 001
> ADD > DEC 01, 1986
> ADD > AP 2%¤ N89409 001
> ADD > DEC 01, 1986
> ADD > AP 2%¤ N89410 001
> ADD > DEC 01, 1986

METAPROTERENOL SULFATE (PAGE 3-140)

SOLUTION; INHALATION

ALUPENT

	BOEHRINGER INGELHEIM	0.4%¤	N18761 002	OCT 10, 1986

METHACHOLINE CHLORIDE (PAGE 3-140)

POWDER FOR RECONSTITUTION; INHALATION

PROVOCHOLINE

	HOFFMANN-LA ROCHE	100MG/VIAL¤	N19193 001	OCT 31, 1986

METHOCARBAMOL (PAGE 3-142)

TABLET; ORAL

METHOCARBAMOL

AA	PIONEER PHARMS	500MG¤	N88731 001	DEC 13, 1985
AA		750MG¤	N89082 001	DEC 13, 1985

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION

FOLEX

AP	ADRIA LABS/ERBAMONT	EQ 250MG BASE/VIAL¤	N88954 001	OCT 24, 1985

FOLEX PFS

AP	ADRIA LABS/ERBAMONT	EQ 25MG BASE/ML¤	N89180 001	JAN 03, 1986
/AP/		/EQ 25MG BASE/ML¤/	/N89181 001/	/JAN 03, 1986/
/AP/		/EQ 25MG BASE/ML¤/	/N89182 001/	/JAN 03, 1986/

METHOTREXATE LPF

AP	LEDERLE LABS/AM CYAN	EQ 25MG BASE/ML	N11719 007	MAR 31, 1982

METHOTREXATE SODIUM

AP	BEN VENUE LABS	EQ 25MG BASE/ML¤	N89340 001	SEP 16, 1986
AP		EQ 25MG BASE/ML¤	N89341 001	SEP 16, 1986
AP		EQ 25MG BASE/ML¤	N89342 001	SEP 16, 1986
AP		EQ 25MG BASE/ML¤	N89343 001	SEP 16, 1986

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION

METHOTREXATE SODIUM

AP	INTL PHARM PRODS	EQ 25MG BASE/ML¤	N88648 001	MAY 09, 1986
AP	LYPHOMED	EQ 2.5MG BASE/ML¤	N89323 001	JUN 13, 1986
AP		EQ 20MG BASE/VIAL¤	N88935 001	OCT 11, 1985
AP		EQ 25MG BASE/ML¤	N89322 001	JUN 13, 1986
AP		EQ 25MG BASE/ML¤	N89263 001	JUN 13, 1986
AP		EQ 50MG BASE/VIAL¤	N88936 001	OCT 11, 1985
AP		EQ 100MG BASE/VIAL¤	N89937 001	OCT 11, 1985
AP	QUAD PHARMS	EQ 25MG BASE/ML¤	N89308 001	JUL 10, 1986
AP		EQ 25MG BASE/ML¤	N89309 001	JUL 10, 1986
AP		EQ 20MG BASE/VIAL¤	N89293 001	JUL 10, 1986
AP		EQ 50MG BASE/VIAL¤	N89294 001	JUL 10, 1986
AP		EQ 100MG BASE/VIAL¤	N89295 001	JUL 10, 1986
AP		EQ 250MG BASE/VIAL¤	N89296 001	JUL 10, 1986

METHOTREXATE

AP	LEDERLE LABS/AM CYAN	EQ 2.5MG BASE/ML	N11719 004	

MEXATE

AP	BRISTOL LABS/B-M	EQ 250MG BASE/VIAL	N86358 004	

METHOXSALEN (PAGE 3-143)

CAPSULE, LIQUID FILLED; ORAL

OXSORALEN-ULTRA

	ELDER PHARMS	10MG¤	N19600 001	OCT 30, 1986

METHYCLOTHIAZIDE (PAGE 3-143)

TABLET; ORAL

METHYCLOTHIAZIDE

AB	PAR PHARMACEUTICAL	2.5MG¤	N89135 001	FEB 12, 1986
AB		5MG¤	N89136 001	FEB 12, 1986

METHYLDOPA (PAGE 3-144)

TABLET; ORAL
METHYLDOPA

AB	BARR LABORATORIES	125MG¤	N70073 001	OCT 09, 1986
AB		250MG¤	N70060 001	OCT 09, 1986
AB		500MG¤	N70074 001	OCT 09, 1986
AB	BOLAR PHARMACEUTICAL	125MG¤	N70245 001	FEB 25, 1986
AB		250MG¤	N70246 001	FEB 25, 1986
AB		500MG¤	N70247 001	FEB 25, 1986
AB	DANBURY PHARMACAL	250MG¤	N70703 001	JUN 06, 1986
AB		500MG¤	N70625 001	JUN 06, 1986
> ADD > AB > ADD >	DURAMED PHARMS	250MG¤	N71006 001	DEC 16, 1986
> ADD > AB > ADD >		500MG¤	N71009 001	DEC 16, 1986
AB	LEDERLE LABS/AM CYAN	125MG¤	N70070 003	OCT 15, 1985
AB		250MG¤	N70084 001	OCT 15, 1985
AB		500MG¤	N70085 001	OCT 15, 1985
> ADD > AB > ADD >	NOVOPHARM	125MG¤	N71105 001	DEC 05, 1986
> ADD > AB > ADD >		250MG¤	N71106 001	DEC 05, 1986
> ADD > AB > ADD >		500MG¤	N71067 001	DEC 05, 1986
AB	PARKE-DAVIS/W-L	125MG¤	N70331 001	APR 15, 1986
AB		250MG¤	N70332 001	APR 15, 1986
AB		500MG¤	N70333 001	APR 15, 1986
AB	PUREPAC/KALIPHARMA	125MG¤	N70749 001	FEB 07, 1986
AB		250MG¤	N70750 001	FEB 07, 1986
AB		500MG¤	N70452 001	FEB 07, 1986
AB	ROXANE LABORATORIES	125MG¤	N70192 001	APR 25, 1986
AB		250MG¤	N70193 001	APR 25, 1986
AB		500MG¤	N70194 001	APR 25, 1986

METHYLDOPA (PAGE 3-144)

TABLET; ORAL
METHYLDOPA

AB	ZENITH LABORATORIES	250MG¤	N70098 001	FEB 20, 1986
AB		500MG¤	N70343 001	FEB 20, 1986

METHYLDOPATE HYDROCHLORIDE (PAGE 3-144)

INJECTABLE; INJECTION
ALDOMET

AP	MS&D/MERCK	50MG/ML	N13401 001	

METHYLDOPATE HCL

AP	ELKINS-SINN/AHROBINS	50MG/ML¤	N70291 001	JUL 01, 1986
AP	LYPHOMED	50MG/ML¤	N70652 001	JUN 03, 1986
AP	QUAD PHARM	50MG/ML¤	N71024 001	SEP 18, 1986

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-145)

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¤	N89186 001	MAR 28, 1986
AP		EQ 500MG BASE/VIAL¤	N89187 001	MAR 28, 1986
AP		EQ 1GM BASE/VIAL¤	N89188 001	MAR 28, 1986
AP		EQ 1GM BASE/VIAL¤	N89189 001	MAR 28, 1986
AP	QUAD PHARMS	EQ 40MG BASE/VIAL¤	N89264 001	JAN 22, 1986
AP		EQ 125MG BASE/VIAL¤	N89265 001	JAN 22, 1986
AP		EQ 500MG BASE/VIAL¤	N89266 001	JAN 22, 1986
AP		EQ 1GM BASE/VIAL¤	N89267 001	JAN 22, 1986

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

AP	LYPHOMED	EQ 10MG BASE/2ML¤	N70293 001 JAN 24, 1986
AP	QUAD PHARMS	EQ 10MG BASE/2ML¤	N70671 001 MAY 27, 1986

REGLAN

AP	AH ROBINS	EQ 10MG BASE/2ML	N17862 001
		EQ 50MG BASE/10ML	N17862 003 AUG 03, 1984
		EQ 150MG BASE/30ML	N17862 002 AUG 03, 1984

TABLET; ORAL

CLOPRA-'YELLOW'

AB	QUANTUM PHARMICS	EQ 10MG BASE¤	N70632 001 OCT 28, 1985

MAXOLON

AB	BEECHAM LABS/BEECHAM	EQ 10MG BASE¤	N70106 001 MAR 04, 1986

METOCLOPRAMIDE HCL

AB	CHELSEA LABORATORIES	EQ 10MG BASE¤	N70453 001 JUN 06, 1986
AB	DANBURY PHARMACAL	EQ 10MG BASE¤	N70511 001 JAN 22, 1986
AB	HALSEY DRUG	EQ 10MG BASE¤	N70906 001 OCT 28, 1986
AB	INTERPHARM	EQ 10MG BASE¤	N71213 001 SEP 24, 1986
AB	PAR PHARMACEUTICAL	EQ 10MG BASE¤	N70342 001 MAR 25, 1986
AB	PUREPAC/KALIPHARMA	EQ 10MG BASE¤	N70581 001 OCT 17, 1985

METRONIDAZOLE (PAGE 3-148)

INJECTABLE; INJECTION

METRONIDAZOLE

AP	CARTER-GLOGAU LABS	500MG/100ML¤	N70170 001 APR 01, 1986

TABLET; ORAL

METRONIDAZOLE

AB	HALSEY DRUG	500MG¤	N70593 001 FEB 27, 1986
AB	MUTUAL PHARM	250MG¤	N70772 001 JUL 16, 1986
AB		500MG¤	N70773 001 JUL 16, 1986
AB	VITARINE	250MG	N18620 001 MAR 04, 1982
AB		500MG	N18620 002 JUN 02, 1983

METRONIDAZOLE (PAGE 3-148)

TABLET; ORAL

METRYL

/AB/	/VITARINE/	/250MG/	/N18620'001/ /MAR 04, 1982/

METRYL 500

/AB/	/VITARINE/	/500MG/	/N18620'002/ /JUN 02, 1983/

METRONIDAZOLE HYDROCHLORIDE (PAGE 3-148)

INJECTABLE; INJECTION

FLAGYL I.V.

AP	SEARLE PHARMS	EQ 500MG BASE/VIAL	N18353 001

METRONIDAZOLE HCL

AP	LYPHOMED	EQ 500MG BASE/VIAL¤	N70295 001 OCT 15, 1985

MEXILETINE HYDROCHLORIDE (PAGE 3-149)

CAPSULE; ORAL

MEXITIL

	BOEHRINGER INGELHEIM	150MG¤	N18873 002 DEC 30, 1985
		200MG¤	N18873 003 DEC 30, 1985
		250MG¤	N18873 004 DEC 30, 1985

MIDAZOLAM HYDROCHLORIDE (PAGE 3-149)

INJECTABLE; INJECTION

VERSED

	HOFFMANN-LA ROCHE	EQ 5MG BASE/ML¤	N18654 001 DEC 20, 1985

MONOOCTANOIN (PAGE 3-150)

LIQUID; PERFUSION, BILIARY

MOCTANIN

	/ASCOT HOSP PHARMS/	/100%/	/N19368'001/ /OCT 29, 1985/
	ETHITEK PHARMS	100%¤	N19368 001 OCT 29, 1985

MORPHINE SULFATE (PAGE 3-150)

INJECTABLE; INJECTION

ASTRAMORPH PF

AP	ASTRA PHARM PRODS	0.5MG/ML¤	N71050 001 OCT 07, 1986
AP		0.5MG/ML¤	N71051 001 OCT 07, 1986
AP		1MG/ML¤	N71052 001 OCT 07, 1986
AP		1MG/ML¤	N71053 001 OCT 07, 1986

DURAMORPH PF

AP	ELKINS-SINN/AHROBINS	0.5MG/ML	N18565 001 SEP 18, 1984
AP		1MG/ML	N18565 002 SEP 18, 1984

NABILONE (PAGE 3-150)

CAPSULE; ORAL

CESAMET

	ELI LILLY	1MG¤	N18677 001 DEC 26, 1985

NADOLOL (PAGE 3-150)

TABLET; ORAL

CORGARD

	ER SQUIBB AND SONS	20MG¤	N18063 005 OCT 28, 1986

NAFCILLIN SODIUM (PAGE 3-150)

INJECTABLE; INJECTION

NAFCIL

> ADD >	AP	BRISTOL LABS/B-M	EQ 1GM BASE/VIAL¤	N62732 001 DEC 23, 1986
> ADD >	AP		EQ 2GM BASE/VIAL¤	N62732 002 DEC 23, 1986

NALLPEN

> ADD >	AP	BEECHAM LABS/BEECHAM	EQ 1GM BASE/VIAL¤	N62755 001 DEC 19, 1986
> ADD >	AP		EQ 2GM BASE/VIAL¤	N62755 002 DEC 19, 1986

UNIPEN

> ADD >	AP	WYETH LABS/AMHO	EQ 500MG BASE/VIAL¤	N62717 001 DEC 16, 1986
> ADD >	AP		EQ 1GM BASE/VIAL¤	N62717 002 DEC 16, 1986
> ADD >	AP		EQ 2GM BASE/VIAL¤	N62717 004 DEC 16, 1986

NALBUPHINE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

NALBUPHINE

AP	LYPHOMED	10MG/ML¤	N70751 001 JUL 02, 1986
AP		20MG/ML¤	N70752 001 SEP 24, 1986 : JUL 02, 1986
AP	QUAD PHARMS	10MG/ML¤	N70692 001 MAR 25, 1986
AP		20MG/ML¤	N70693 001 SEP 24, 1986 : MAR 25, 1986

NUBAIN

AP	DUPONT PHARMS/DUPONT	10MG/ML	N18024 001
AP		20MG/ML	N18024 002 MAY 27, 1982

NALIDIXIC ACID (PAGE 3-151)

TABLET; ORAL

NALIDIXIC ACID

AB	BARR LABORATORIES	250MG¤	N70270 001 JUN 29, 1988 : MAR 28, 1986
AB		500MG¤	N70271 001 JUN 29, 1988 : MAR 28, 1986
AB		1GM¤	N70272 001 JUN 29, 1988 : MAR 28, 1986

NEGGRAM

AB	WINTHROP-BREON/STERL	250MG	N14214 002
AB		500MG	N14214 004
AB		1GM	N14214 005

NALOXONE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

NALOXONE

AP	ELKINS-SINN/AHROBINS	0.4MG/ML¤	N70298 001 SEP 24, 1986 : OCT 22, 1985
AP		0.4MG/ML¤	N70299 001 SEP 24, 1986 : OCT 22, 1985
AP		0.4MG/ML¤	N70496 001 SEP 24, 1986 : OCT 22, 1985
AP	INTL MEDICATION SYS	0.4MG/ML¤	N70417 001 SEP 24, 1986 : NOV 06, 1985
AP		0.4MG/ML¤	N70639 001 SEP 24, 1986 : JAN 17, 1986
AP	WYETH LABS/AMHO	0.02MG/ML¤	N70188 001 SEP 24, 1986 : OCT 02, 1985
AP		0.02MG/ML¤	N70189 001 SEP 24, 1986 : OCT 02, 1985
AP		0.4MG/ML¤	N70190 001 SEP 24, 1986 : OCT 02, 1985
AP		0.4MG/ML¤	N70191 001 SEP 24, 1986 : OCT 02, 1985

NALOXONE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

NALOXONE HCL

	AP	LYPHOMED	0.02MG/ML¤	N70648 001 NOV 17, 1986
	AP		0.02MG/ML¤	N70661 001 NOV 17, 1986
	AP		0.4MG/ML¤	N70649 001 NOV 17, 1986
> AAD >	AP	QUAD PHARMS	0.02MG/ML¤	N70678 001 DEC 18, 1986
> ADD >	AP		0.4MG/ML¤	N70679 001 DEC 18, 1986
> ADD >	AP		1MG/ML¤	N70680 001 DEC 18, 1986
	AP	WINTHROP-BREON/STERL	0.02MG/ML¤	N70171 001 SEP 24, 1986 : APR 18, 1986
	AP		0.4MG/ML¤	N70172 001 SEP 24, 1986 : APR 18, 1986

NARCAN

	AP	DUPONT PHARMS/DUPONT	0.02MG/ML	N16636 002
	AP		0.4MG/ML	N16636 001
> ADD >	AP	/#/	1MG/ML	N16636 003 JUN 14, 1982

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE (PAGE 3-151)

TABLET; ORAL

TALWIN NX

/WINTHROP-BREON/STERL/0.5 MG;EQ 50MG BASE/ /N18733 001/ /DEC 16, 1982/

	WINTHROP-BREON/STERL	EQ 0.5MG BASE; EQ 50MG BASE	N18733 001 DEC 16, 1982

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION

DECA-DURABOLIN

AO		ORGANON/AKZONA	50MG/ML¤	N13132 001 JUN 12, 1986
AO			100MG/ML¤	N13132 002 JUN 12, 1986
AO			200MG/ML¤	N13132 003 JUN 12, 1986

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION

NANDROLONE DECANOATE

AO		CARTER-GLOGAU LABS	50M/ML	N86385 001 JAN 13, 1984
AO			100MG/ML	N86598 001 JAN 13, 1984
AO		LEMMON	50MG/ML¤	N88554 001 FEB 10, 1986
AO			50MG/ML	N87598 001 OCT 06, 1983
AO		QUAD PHARMS	50MG/ML¤	N89248 001 JUN 25, 1986
AO			100MG/ML¤	N89249 001 JUN 25, 1986
AO			200MG/ML¤	N89250 001 JUN 25, 1986

NANDROLONE PHENPROPIONATE (PAGE 3-151)

INJECTABLE; INJECTION

NANDROLONE PHENPROPIONATE

AO		QUAD PHARMS	25MG/ML¤	N89297 001 OCT 01, 1986
AO			50MG/ML¤	N89298 001 OCT 01, 1986

NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-153)

SOLUTION; IRRIGATION

NEOMYCIN AND POLYMYXIN B SULFATES

AT		CARTER-GLOGAU LABS	EQ 40MG BASE/ML; 200,000 UNITS/ML¤	N62664 001 APR 08, 1986

NEOSPORIN G.U. IRRIGANT

AT		BURROUGHS WELLCOME	EQ 40MG BASE/ML; 200,000 UNITS/ML	N60707 001

NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE (3-153)

CREAM; TOPICAL

MYTREX A

AT		SAVAGE LABS/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62598 001 JUL 21, 1986

NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE

AT		E FOUGERA/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62600 001 JUL 21, 1986
AT		PHARMADERM/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62595 001 JUL 21, 1986

NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE (3-153)

OINTMENT; TOPICAL

	MYTREX A			
AT	SAVAGE LABS/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62609 001	MAY 23, 1986
	NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE			
AT	E FOUGERA/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62608 001	MAY 23, 1986
AT	PHARMADERM/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62607 001	MAY 23, 1986

NIFEDIPINE (PAGE 3-154)

CAPSULE; ORAL

	ADALAT			
AB	MILES PHARM/MILES	10MG¤	N19478 001	NOV 27, 1985
AB		20MG¤	N19478 002	SEP 17, 1986
	PROCARDIA			
AB	PFIZER LABS/PFIZER	10MG	N18482 001	
AB		20MG¤	N18482 002	JUL 24, 1986

NITROGLYCERIN (PAGE 3-154)

AEROSOL; ORAL

	NITROLINGUAL			
	G POHL-BOSKAMP	0.4MG/SPRAY¤	N18705 001	OCT 31, 1985

INJECTABLE; INJECTION

	NITROGLYCERIN			
AP	INTL MEDICATION SYS	5MG/ML¤	N70026 001	SEP 10, 1985
AP	LYPHOMED	5MG/ML¤	N70077 001	DEC 13, 1985
AP	SOLOPAK LABORATORIES	5MG/ML¤	N70633 001	JUN 19, 1986
AP		5MG/ML¤	N70634 001	JUN 19, 1986

/NOMIFENSINE MALEATE/(PAGE 3-155)

	/MERITAL/			
	/¤/HOECHST-ROUSSEL/	/25MG/	/N18224 001/	/DEC 31, 1984/
	/¤/	/50MG/	/N18224 002/	/DEC 31, 1984/

NORFLOXACIN (PAGE 3-155)

TABLET; ORAL

	NOROXIN			
	MSD RES LABS	400MG	N19384 002	OCT 31, 1986

NYSTATIN (PAGE 3-156)

OINTMENT; TOPICAL

	MYKINAC			
AT	NMC LABORATORIES	100,000 UNITS/GM¤	N62731 001	SEP 22, 1986

POWDER; ORAL

	NILSTAT			
AA	LEDERLE LABS/AM CYAN	100%	N50576 001	DEC 22, 1983
	NYSTATIN			
AA	PADDOCK LABORATORIES	100%¤	N62613 001	NOV 26, 1985

SUSPENSION; ORAL

	NYSTATIN			
AA	NASKA PHARMACAL	100,000 UNITS/ML¤	N62571 001	OCT 29, 1985

TABLET; ORAL

	NYSTATIN			
AA	LEMMON	500,000 UNITS	N62506 001	JAN 16, 1984
AA	PHARM BASICS	500,000 UNITS¤	N62524 001	NOV 26, 1985

TABLET; VAGINAL

	NYSTATIN			
AT	SIDMAK LABORATORIES	100,000 UNITS¤	N62615 001	OCT 17, 1985

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

CREAM; TOPICAL

	MYCO-TRIACET II			
AT	LEMMON	100,000 UNITS/GM;0.1%¤	N61954 002	SEP 20, 1985
	MYTREX F			
AT	SAVAGE LABS/ALTANA	100,000 UNITS/GM;0.1%¤	N62597 001	OCT 08, 1985

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

CREAM; TOPICAL

NYSTATIN-TRIAMCINOLONE ACETONIDE

AT	E FOUGERA/ALTANA	100,000 UNITS/GM;0.1%	N62599 001	OCT 08, 1985
AT	PHARMADERM/ALTANA	100,000 UNITS/GM;0.1%	N62596 001	OCT 08, 1985

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT	PHARMAFAIR	100,000 UNITS/GM;0.1%	N62657 001	JUL 30, 1986

OINTMENT; TOPICAL

MYCO-TRIACET II

AT	LEMMON	100,000 UNITS/GM;0.1%	N62045 002	NOV 26, 1985

MYCOLOG-II

AT	ER SQUIBB AND SONS	100,000 UNITS/GM;0.1%	N60572 001	JUN 28, 1985

MYTREX F

AT	SAVAGE LABS/ALTANA	100,000 UNITS/GM;0.1%	N62601 001	OCT 09, 1985

NYSTATIN-TRIAMCINOLONE ACETONIDE

AT	E FOUGERA/ALTANA	100,000 UNITS/GM;0.1%	N62602 001	OCT 09, 1985
AT	PHARMADERM/ALTANA	100,000 UNITS/GM;0.1%	N62603 001	OCT 09, 1985

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT	CLAY-PARK LABS	100,000 UNITS/GM;0.1%	N62280 002	OCT 10, 1985
AT	PHARMAFAIR	100,000 UNITS/GM;0.1%	N62656 002	JUL 30, 1986

OXACILLIN SODIUM (PAGE 3-157)

INJECTABLE; INJECTION

BACTOCILL

> ADD >	AP	BEECHAM LABS/BEECHAM	EQ 1GM BASE/VIAL%	N62736 001	DEC 19, 1986
> ADD >	AP		EQ 2GM BASE/VIAL%	N62736 002	DEC 19, 1986

PROSTAPHLIN

> ADD >	AP	BRISTOL LABS/B-M	EQ 1GM BASE/VIAL%	N62737 001	DEC 23, 1986
> ADD >	AP		EQ 2GM BASE/VIAL%	N62737 002	DEC 23, 1986

OXYPHENBUTAZONE (PAGE 3-159)

TABLET; ORAL

OXYPHENBUTAZONE

AB	@ BOLAR PHARMACEUTICAL	100MG	N88399 001	SEP 17, 1984

PARGYLINE HYDROCHLORIDE (PAGE 3-160)

TABLET; ORAL

EUTONYL

@	ABBOTT LABORATORIES	50MG	N13448 004	

PENICILLIN G POTASSIUM (PAGE 3-161)

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN G POTASSIUM

AA	@ MYLAN PHARMS	200,000 UNITS/5ML	N60752 003	
AA	@	250,000 UNITS/5ML	N60752 002	
AA	@	400,000 UNITS/5ML	N60752 001	

PERMETHRIN (PAGE 3-164)

LOTION; TOPICAL

NIX

	BURROUGHS WELLCOME	1%	N19435 001	MAR 31, 1986

PHENTERMINE HYDROCHLORIDE (PAGE 3-167)

CAPSULE; ORAL

/ADIPEX/

/AA/	/LEMMON/	/30MG/	N87126 001	

PHENTERMINE HCL

AA	DURAMED PHARMS	30MG%	N88948 001	APR 25, 1986
AA	LEMMON	30MG%	N87777 001	NOV 01, 1985
AA		30MG	N87126 001	

PHENYLBUTAZONE (PAGE 3-168)

CAPSULE; ORAL

PHENYLBUTAZONE

AB	BARR LABORATORIES	100MG%	N88994 001	DEC 04, 1985

TABLET; ORAL

PHENYLBUTAZONE

AB	BARR LABORATORIES	100MG%	N88863 001	DEC 04, 1985

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-168)

SYRUP; ORAL
PROMETHAZINE VC PLAIN
AA HR CENCI LABS 5MG/5ML;6.25MG/5ML¤ N88815 001 NOV 22, 1985

PHENYTOIN SODIUM, EXTENDED (PAGE 3-169)

CAPSULE; ORAL
EXTENDED PHENYTOIN SODIUM
>ADD > AB SIDMAK LABORATORIES 100MG¤ N89441 001 DEC 18, 1986
>ADD > /EXTENDED PHENYTOIN SODIUM/
/AB/ /BOLAR PHARMACEUTICAL/100MG/ /N88711 001/ /DEC 21, 1984/
/SETROL/
PHENYTEX
AB BOLAR PHARMACEUTICAL 100MG N88711 001 DEC 21, 1984

PHENYTOIN SODIUM, PROMPT (PAGE 3-169)

CAPSULE; ORAL
PHENYTOIN SODIUM
/BX/ /DANBURY PHARMACAL/ /100MG/ /N80905 001/
/BX/ /ZENITH LABORATORIES//100MG/ /N80259 001/
PROMPT PHENYTOIN SODIUM
BX DANBURY PHARMACAL 100MG N80905 001
BX ZENITH LABORATORIES 100MG N80259 001

PIPERAZINE CITRATE (PAGE 3-170)

TABLET; ORAL
ANTEPAR
@ BURROUGHS WELLCOME EQ 500MG BASE N09102 003

>ADD > PIRBUTEROL ACETATE (PAGE 3-170)

>ADD > AEROSOL; INHALATION
>ADD > EXIREL
>ADD > PFIZER LABS/PFIZER EQ 0.2MG BASE/INH¤ N19009 001 DEC 30, 1986
>ADD >

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE (PAGE 3-170)

SOLUTION; ORAL
OCL
@ ABBOTT LABORATORIES 6GM/100ML;75MG/100ML;168MG/100ML; 146MG/100ML; 1.29GM/100ML¤ N19284 001 APR 30, 1986

POTASSIUM CHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION
POTASSIUM CHLORIDE
AP MAURRY BIOLOGICAL 2MEQ/ML¤ N88286 001 SEP 05, 1985

TABLET, CONTROLLED RELEASE; ORAL
K-DUR 10
BC KEY PHARMACEUTICALS 10MEQ¤ N19439 002 JUN 13, 1986
K-DUR 20
KEY PHARMACEUTICALS 20MEQ¤ N19439 001 JUN 13, 1986
>DLT > /KALINORM/
>ADD > TEN-K
/BC/ /A/S BENZON/ /10MEQ¤/ /N19381 001/ /APR 16, 1986/
BC CIBA/CIBA-GEIGY 10MEQ N19381 001 APR 16, 1986
KLOR-CON
BC UPSHER-SMITH LABS 8MEQ¤ N19123 001 APR 17, 1986
BC 10MEQ¤ N19123 002 APR 17, 1986
SLOW-K
BC CIBA-GEIGY 8MEQ N17476 002

POTASSIUM CITRATE (PAGE 3-173)

/TABLET; ORAL/
TABLET, CONTROLLED RELEASE; ORAL
/POTASSIUM CITRATE/
UROCIT-K
UNIV TX HLTH SCI CTR 5MEQ¤ N19071 001 AUG 30, 1985

QUINIDINE GLUCONATE (PAGE 3-186)

TABLET, CONTROLLED RELEASE; ORAL

	QUINALAN			
BC	LANNETT	324MG¤		N88081 001
				FEB 10, 1986
	QUINIDINE GLUCONATE			
AB	SUPERPHARM	324MG¤		N89164 001
				NOV 21, 1985

RANITIDINE HYDROCHLORIDE (PAGE 3-187)

TABLET; ORAL

	ZANTAC			
	GLAXO	EQ 150MG BASE		N18703 001
				JUN 09, 1983
	ZANTAC 300			
	GLAXO	EQ 300MG BASE¤		N18703 002
				DEC 09, 1985

> ADD > RANITIDINE HYDROCHLORIDE; SODIUM CHLORIDE (PAGE 3-187)

> ADD > INJECTABLE; INJECTION

> ADD >	ZANTAC IN PLASTIC CONTAINER			
> ADD >	GLAXO	EQ 50MG BASE/100ML;		
> ADD >		450MG/100ML¤		N19593 001
> ADD >				DEC 17, 1986

RIBAVIRIN (PAGE 3-189)

POWDER FOR RECONSTITUTION; INHALATION

	VIRAZOLE			
	VIRATEK	6GM/VIAL¤		N18859 001
				DEC 31, 1985

RITODRINE HYDROCHLORIDE (PAGE 3-189)

INJECTABLE; INJECTION

	RITODRINE HCL			
AP	QUAD PHARMS	10MG/ML¤		N70700 001
				OCT 06, 1986
AP		15MG/ML¤		N70701 001
				OCT 06, 1986
	YUTOPAR			
AP	ASTRA PHARM PRODS	10MG/ML		N18580 001
AP		15MG/ML		N18580 002

SECRETIN (PAGE 3-190)

INJECTABLE; INJECTION

	SECRETIN-KABI			
	PHARMACIA/PHARMACIA	75CU/VIAL		N18290 001

SILVER SULFADIAZINE (PAGE 3-191)

CREAM; TOPICAL

	SILVADENE			
AB	MARION LABORATORIES	1%		N17381 001
	SSD			
AB	TRAVENOL LABS	1%		N18578 001
				FEB 25, 1982
	ULTRA DERM			
AB	CHESEBROUGH-PONDS	1%¤		N18810 001
				DEC 23, 1985

SODIUM BICARBONATE (PAGE 3-191)

INJECTABLE; INJECTION

	SODIUM BICARBONATE IN PLASTIC CONTAINER			
	ABBOTT LABORATORIES	0.9MEQ/ML¤		N19443 001
				JUN 03, 1986
		1MEQ/ML¤		N19443 002
				JUN 03, 1986

SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-191)

GRANULE, EFFERVESCENT; ORAL

	BAROS			
	MALLINCKRODT	460MG/GM;420MG/GM¤		N18509 001
				AUG 07, 1985

SODIUM CHLORIDE (PAGE 3-191)

INJECTABLE; INJECTION

	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER			
AP	ABBOTT LABORATORIES	900MG/100ML¤		N19480 001
				SEP 17, 1985
AP	TRAVENOL LABS	9MG/ML¤		N16677 004
				OCT 30, 1985

SODIUM IODIDE, I-123 (PAGE 3-193)

CAPSULE; ORAL
SODIUM IODIDE I-123
@ BENEDICT NUCLR PHARM 400 UCI — N18671 003 MAY 27, 1982

SODIUM NITROPRUSSIDE (PAGE 3-194)

INJECTABLE; INJECTION
NITROPRESS
AP ABBOTT LABORATORIES 50MG/VIAL¤ — N70566 001 JUN 09, 1986

SODIUM POLYSTYRENE SULFONATE (PAGE 3-195)

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
AA ROXANE LABORATORIES 15GM/60ML¤ — N89049 001 NOV 17, 1986

SOMATREM (PAGE 3-195)

INJECTABLE; INJECTION
PROTROPIN
GENENTECH 5MG/VIAL¤ — N19107 001 OCT 17, 1985

SOMATROPIN (PAGE 3-195)

INJECTABLE; INJECTION
ASELLACRIN 10
@ SERONO LABS 10 IU/VIAL — N17726 001
ASELLACRIN 2
@ SERONO LABS 2 IU/VIAL — N17726 002 JUL 21, 1983

CRESCORMON
@ KABIVITRUM 4 IU/VIAL — N17992 001

SPIRONOLACTONE (PAGE 3-196)

TABLET; ORAL
SPIRONOLACTONE
AB MUTUAL PHARMACAL 25MG¤ — N89424 001 JUL 23, 1986
AB SUPERPHARM 25MG¤ — N89364 001 NOV 07, 1986

STANOZOLOL (PAGE 3-196)

TABLET; ORAL
WINSTROL
WINTHROP-BREON/STERL 2MG¤ — N12885 001 MAY 14, 1984

SULCONAZOLE NITRATE (PAGE 3-197)

SOLUTION; TOPICAL
SULCOSYN
SYNTEX LABS/SYNTEX 1%¤ — N18738 001 AUG 30, 1985

SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE; UREA (PAGE 3-197)

CREAM; VAGINAL
GYNE-SULF
AT G AND W LABORATORIES 3.7%;2.86%;3.42%;0.64%¤ — N88607 001 JUN 09, 1986

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

SUSPENSION; ORAL
SEPTRA GRAPE
AB BURROUGHS WELLCOME 200MG/5ML;40MG/5ML¤ — N17598 002 FEB 12, 1986

SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB PLANTEX/IKAPHARM 200MG/5ML;40MG/5ML¤ — N70028 001 JUN 02, 1987 : OCT 29, 1985

SULMEPRIM
AB MY-K LABS 200MG/5ML;40MG/5ML¤ — N70063 001 AUG 01, 1986

SULMEPRIM PEDIATRIC
AB MY-K LABS 200MG/5ML;40MG/5ML¤ — N70064 001 AUG 01, 1986

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB CORD LABORATORIES 400MG;80MG¤ — N70889 001 NOV 13, 1986
AB 800MG;160MG¤ — N70890 001 NOV 13, 1986
AB MUTUAL PHARM 400MG;80MG¤ — N71016 001 AUG 25, 1986
AB 800MG;160MG¤ — N71017 001 AUG 25, 1986
AB PHARM BASICS 400MG;80MG¤ — N70203 001 /JUN 02, 1987/ : NOV 08, 1985
AB 800MG;160MG¤ — N70204 001 /JUN 02, 1987/ : NOV 08, 1985

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	SIDMAK LABORATORIES	400MG;80MG¤	N70215 001	/JUN 02, 1987 ‡/SEP 10, 1985
AB		800MG;160MG	N70216 001	/JUN 02, 1987 ‡/SEP 10, 1985

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

AB	PLANTEX/IKAPHARM	800MG;160MG¤	N70037 001	JUN 02, 1987 : SEP 19, 1985

SULFAMETHOXAZOLE AND TRIMETHOPRIM SINGLE STRENGTH

AB	PLANTEX/IKAPHARM	400MG;80MG¤	N70030 001	JUN 02, 1987 : SEP 19, 1985

SULFANILAMIDE (PAGE 3-199)

CREAM; VAGINAL

	/AVC/			
/AT/	/MERRELL DOW/DOW CHEM/	15%¤/	/N06536 003/	/SEP 04, 1986/

VAGITROL

	LEMMON	15%¤	N88718 001	SEP 19, 1985

/SUPPOSITORY; VAGINAL/

	/AVC/			
	/MERRELL DOW/DOW CHEM/	1.65GM¤/	/N06536 004/	/SEP 04, 1986/

SULFINPYRAZONE (PAGE 3-200)

CAPSULE; ORAL

SULFINPYRAZONE

AB	PAR PHARMACEUTICAL	200MG¤	N88934 001	SEP 06, 1985

TABLET; ORAL

SULFINPYRAZONE

AB	PAR PHARMACEUTICAL	100MG¤	N88933 001	SEP 06, 1985

SULFISOXAZOLE DIOLAMINE (PAGE 3-200)

SOLUTION/DROPS; OPHTHALMIC

SULFISOXAZOLE DIOLAMINE

AT	@ BARNES-HIND PHARMS	EQ 4% BASE	N84148 001

GANTRISIN

AT	HOFFMAN-LAROCHE	EQ 4% BASE	N07757 002

SUPROFEN (PAGE 3-201)

CAPSULE; ORAL

SUPROL

	ORTHO PHARMACEUTICAL	200MG¤	N18217 001 DEC 24, 1985

TECHNETIUM, TC-99M, SULFUR COLLOID (PAGE 3-203)

INJECTABLE; INJECTION

/TECHNETIUM TC 99M SULFUR COLLOID/			
/GAMMA DIAG LABS/	/3MCI/ML/		/N17724 001/

SOLUTION; INJECTION, ORAL

TECHNETIUM TC 99M SULFUR COLLOID

GAMMA DIAG LABS	3MCI/ML	N17724 001

TECHNETIUM, TC-99M, LIDOFENIN KIT (PAGE 3-202)

INJECTABLE; INJECTION

TECHNESCAN HIDA KIT

	MS&D RES LABS/MERCK	N/A¤	N18489 001 OCT 31, 1986

TECHNETIUM, TC-99M, SULFUR COLLOID KIT (PAGE 3-203)

INJECTABLE; INJECTION

	/SULFUR COLLOID KIT/			
/AP/	/SYNCOR INTL/	/N/A/	/N17858 001/	

AN-SULFUR COLLOID

AP	CIS-US	N/A	N17858 001	

	/TECHNECOLL/			
/AP/	/MALLINCKRODT/	/N/A/	/N17059 001/	
	/TESULOID/			
/AP/	/ER SQUIBB AND SONS/	/N/A/	/N16923 001/	

SOLUTION; INJECTION, ORAL

TECHNECOLL

AP	MALLINCKRODT	N/A	N17059 001

TESULOID

AP	ER SQUIBB AND SONS	N/A	N16923 001

TEMAZEPAM (PAGE 3-203)

CAPSULE; ORAL

RESTORIL

AB	SANDOZ PHARMS/SANDOZ	15MG	N18163 001
AB		30MG	N18163 002

TEMAZEPAM (PAGE 3-203)

CAPSULE; ORAL

	/~~SOMAZ~~/		
	TEMAZ		
AB	QUANTUM PHARMICS	15MG¤	N70564 001 OCT 15, 1985
AB		30MG¤	N70547 001 OCT 15, 1985
	TEMAZEPAM		
AB	BARR LABORATORIES	15MG¤	N71174 001 JUL 10, 1986
AB		30MG¤	N71175 001 JUL 10, 1986
AB	COLMED LABORATORIES	15MG¤	N70489 001 JUL 07, 1986
AB		30MG¤	N70490 001 JUL 07, 1986
AB	MYLAN PHARMS	15MG¤	N70919 001 JUL 07, 1986
AB		30MG¤	N70920 001 JUL 07, 1986

TESTOSTERONE ENANTHATE (PAGE 3-204)

INJECTABLE; INJECTION

	TESTOSTERONE ENANTHATE		
AO	QUAD PHARMS	100MG/ML¤	N89324 001 SEP 16, 1986
AO		200MG/ML¤	N89325 001 SEP 16, 1986

TESTOSTERONE PROPIONATE (PAGE 3-204)

INJECTABLE; INJECTION

	TESTOSTERONE PROPIONATE		
AO	QUAD PHARMS	100MG/ML¤	N89283 001 NOV 03, 1986

TETRACYCLINE HYDROCHLORIDE (PAGE 3-205)

CAPSULE; ORAL

	TETRACYCLINE HCL		
AB	PRIVATE FORMULATIONS	250MG¤	N62686 001 JUL 24, 1986
AB		500MG¤	N62686 002 JUL 24, 1986

THEOPHYLLINE (PAGE 3-206)

CAPSULE; ORAL

	~~ELIXOPHYLLIN~~		
/~~AA~~/	/~~BERLEX/SCHERING~~/	/~~100MG~~/	/~~N85545 001~~/ /~~JUL 31, 1984~~/
/~~AA~~/		/~~200MG~~/	/~~N83921 001~~/ /~~JUL 31, 1984~~/
	SOMOPHYLLIN-T		
/~~BP~~/	/~~FISONS~~/	/~~100MG~~/	/~~N87155 001~~/ /~~FEB 25, 1985~~/
/~~BP~~/		/~~200MG~~/	/~~N87155 002~~/ /~~FEB 25, 1985~~/
BX	BERLEX/SCHERING	100MG	N85545 001 JUL 31, 1984
BX		200MG	N83921 001 JUL 31, 1984
	SOMOPHYLLIN-T		
BX	FISONS	100MG	N87155 001 FEB 25, 1985
BX		200MG	N87155 002 FEB 25, 1985
BX		250MG	N87155 003 FEB 25, 1985
	THEOPHYLLINE		
BX	RP SCHERER	100MG¤	N84731 002 NOV 07, 1986
BX		200MG¤	N84731 001 NOV 07, 1986
BX		250MG¤	N84731 003 NOV 07, 1986

CAPSULE, CONTROLLED RELEASE; ORAL

	AEROLATE III		
	FLEMING	65MG¤	N85075 003 NOV 24, 1986
	AEROLATE JR		
BC	FLEMING	130MG¤	N85075 002 NOV 24, 1986
	AEROLATE SR		
BC	FLEMING	260MG¤	N85075 001 NOV 24, 1986
	THEO-DUR SPRINKLE		
BC	KEY PHARMACEUTICALS	50MG¤	N88022 001 SEP 10, 1985
BC		125MG¤	N88016 001 SEP 10, 1985
BC		200MG¤	N87995 001 SEP 10, 1985
		75MG¤	N88015 001 SEP 10, 1985
	THEOPHYLLINE-SR		
BC	RP SCHERER	300MG¤	N88255 001 JUN 12, 1986

THEOPHYLLINE (PAGE 3-206)

ELIXIR; ORAL

THEOPHYL 225

/KNOLL PHARMACEUTICAL/ 112.5MG/15ML / /N86485 001/

MCNEIL PHARM 112.5MG/15ML N86485 001

SOLUTION; ORAL

>ADD> AEROLATE

>ADD> FLEMING 150MG/15ML¤ N89141 001

>ADD> DEC 03, 1986

SYRUP; ORAL

ACCURBRON

AA MERRELL DOW/DOW CHEM 150MG/15ML¤ N88746 001

NOV 22, 1985

THEOPHYLLINE

AA NATL PHARM MFG/BARRE 150MG/15ML N86545 001

TABLET; ORAL

QUIBRON-T

MEAD JOHNSON/B-M 300MG¤ N88656 001

AUG 22, 1985

SLO-PHYLLIN

/BD/ /WILLIAM H RORER/ /100MG/ /N85202 001/

/BD/ /200MG/ /N85204 001/

AB WILLIAM H RORER 100MG N85202 001

AB 200MG N85204 001

THEOPHYL-225

/KNOLL PHARMACEUTICAL/ 225MG/ /N84726 001/

MCNEIL PHARM 225MG N84726 001

TABLET, CHEWABLE; ORAL

THEOPHYL

MCNEIL PHARM 100MG¤ N86506 001

SEP 12, 1985

TABLET, CONTROLLED RELEASE; ORAL

THEO-DUR

KEY PHARMACEUTICALS 450MG¤ N89131 001

JUN 25, 1986

THIORIDAZINE HYDROCHLORIDE (PAGE 3-209)

CONCENTRATE; ORAL

THIORIDAZINE HCL INTENSOL

AA ROXANE LABORATORIES 30MG/ML¤ N88941 001

DEC 16, 1985

AA 100MG/ML¤ N88942 001

DEC 16, 1985

THIORIDAZINE HYDROCHLORIDE (PAGE 3-209)

TABLET; ORAL

THIORIDAZINE HCL

AB CORD LABORATORIES 150MG¤ N88136 001

SEP 17, 1986

AB 200MG¤ N88137 001

SEP 17, 1986

AB MUTUAL PHARM 10MG¤ N89431 001

AUG 01, 1986

AB 25MG¤ N89432 001

AUG 01, 1986

AB 50MG¤ N89433 001

AUG 01, 1986

TICARCILLIN DISODIUM (PAGE 3-211)

INJECTABLE; INJECTION

TICAR

>ADD> BEECHAM LABS/BEECHAM EQ 3GM BASE/VIAL¤ N62690 001

>ADD> DEC 19, 1986

TIMOLOL MALEATE (PAGE 3-211)

SOLUTION/DROPS; OPHTHALMIC

TIMOPTIC IN OCUDOSE

MSD RES LABS EQ 0.25% BASE¤ N19463 001

NOV 05, 1986

EQ 0.5% BASE¤ N19463 002

NOV 05, 1986

>ADD> TIOCONAZOLE (PAGE 3-211)

>ADD> OINTMENT; VAGINAL

>ADD> VAGISTAT

>ADD> ROERIG/PFIZER 6.5%¤ N19355 001

>ADD> DEC 30, 1986

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL

TOLAZAMIDE

AB BARR LABORATORIES 100MG¤ N70162 001

JAN 14, 1986

AB 250MG¤ N70163 001

JAN 14, 1986

AB 500MG¤ N70164 001

JAN 14, 1986

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL
TOLAZAMIDE

AB	BOLAR PHARMACEUTICAL	100MG¤	N70242 001	AUG 01, 1986
AB		250MG¤	N70243 001	AUG 01, 1986
AB		500MG¤	N70244 001	AUG 01, 1986
AB	CHELSEA LABORATORIES	100MG¤	N70285 001	JAN 09, 1986
AB		250MG¤	N70286 001	JAN 09, 1986
AB		500MG¤	N70287 001	JAN 09, 1986
AB	COLMED LABORATORIES	250MG¤	N70168 001	APR 02, 1986
AB		500MG¤	N70169 001	APR 02, 1986
AB	CORD LABORATORIES	250MG¤	N70289 001	MAR 13, 1986
AB		500MG¤	N70290 001	MAR 13, 1986
AB	DANBURY PHARMACAL	100MG¤	N70513 001	JAN 09, 1986
AB		250MG¤	N70514 001	JAN 09, 1986
AB		500MG¤	N70515 001	JAN 09, 1986
AB	DURAMED PHARMS	100MG¤	N70165 001	JAN 10, 1986
AB		250MG¤	N70166 001	JAN 10, 1986
AB		500MG¤	N70167 001	JAN 10, 1986
AB	INTERPHARM	250MG¤	N71270 001	SEP 23, 1986
AB		500MG¤	N71271 001	SEP 23, 1986
AB	MYLAN PHARMS	250MG¤	N70259 001	JAN 02, 1986
AB		500MG¤	N70913 001	MAR 17, 1986
AB	PAR PHARMACEUTICAL	100MG¤	N70159 001	JAN 06, 1986
AB		250MG¤	N70160 001	JAN 06, 1986
AB		500MG¤	N70161 001	JAN 06, 1986
AB	SUPERPHARM	250MG¤	N70763 001	JUN 16, 1986
AB		500MG¤	N70764 001	JUN 16, 1986

> ADD > TRANEXAMIC ACID (PAGE 3-212)

> ADD > INJECTABLE; INJECTION
> ADD > CYKLOKAPRON

> ADD >	KABIVITRUM	100MG/ML¤	N19281 001	DEC 30, 1986

> ADD > TABLET; ORAL
> ADD > CYKLOKAPRON

> ADD >	KABIVITRUM	500MG¤	N19280 001	DEC 30, 1986

TRAZODONE HYDROCHLORIDE (PAGE 3-212)

TABLET; ORAL
DESYREL

AB	MEAD JOHNSON/B-M	50MG	N18207 001	
AB		100MG	N18207 002	

TRAZODONE HCL

AB	AM THERAPEUTICS	50MG¤	N71139 001	OCT 29, 1986
AB		100MG¤	N71140 001	OCT 29, 1986
AB	BOLAR PHARMACEUTICAL	50MG¤	N71112 001	NOV 17, 1986
AB		100MG¤	N71113 001	NOV 17, 1986
AB	CHELSEA LABORATORIES	50MG¤	N70568 001	OCT 10, 1986
AB		100MG¤	N70569 001	OCT 10, 1986
AB	DANBURY PHARMACAL	50MG¤	N70857 001	OCT 10, 1986
AB		100MG¤	N70858 001	OCT 10, 1986
> ADD > AB	QUANTUM PHARMICS	50MG¤	N70942 001	DEC 01, 1986
> ADD > AB		100MG¤	N70921 001	DEC 01, 1986

TRIAMCINOLONE ACETONIDE (PAGE 3-213)

LOTION; TOPICAL
TRIAMCINOLONE ACETONIDE

AT	THAMES PHARMACAL	0.1%¤	N89129 001	AUG 14, 1986

PASTE; DENTAL
KENALOG IN ORABASE

AT	ER SQUIBB AND SONS	0.1%	N12097 001	

ORACORT

AT	TARO PHARMS	0.1%¤	N70730 001	OCT 01, 1986

TRIENTINE HYDROCHLORIDE (PAGE 3-216)

CAPSULE; ORAL
CUPRID

	MS&D RES LABS/MERCK	250MG¤	N19194 001 NOV 08, 1985

TRIMETHOBENZAMIDE HYDROCHLORIDE (PAGE 3-217)

INJECTABLE; INJECTION
TRIMETHOBENZAMIDE HCL

AP	SOLOPAK LABORATORIES	100MG/ML¤	N88960 001 APR 04, 1986
AP		100MG/ML¤	N89043 001 APR 04, 1986
AP		100MG/ML¤	N89094 001 APR 04, 1986

TRIMETHOPRIM (PAGE 3-218)

TABLET; ORAL
TRIMETHOPRIM

AB	BARR LABORATORIES	100MG¤	N70494 001 JAN 22, 1986
AB		200MG¤	N70495 001 SEP 24, 1986 : MAR 14, 1986

TROPICAMIDE (PAGE 3-219)

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE

AT	MAURRY BIOLOGICAL	1%¤	N88447 001 AUG 28, 1985

UROFOLLITROPIN (PAGE 3-220)

INJECTABLE; INJECTION
METRODIN

	SERONO LABS	75IU/AMP¤	N19415 001 SEP 18, 1986

VALPROATE SODIUM (PAGE 3-220)

SYRUP; ORAL
DEPAKENE

AA	ABBOTT LABORATORIES	EQ 250MG BASE/5ML	N18082 001

MYPROIC ACID

AA	MY-K LABS	EQ 250MG BASE/5ML¤	N70868 001 JUL 01, 1986

VALPROIC ACID (PAGE 3-220)

CAPSULE; ORAL
DEPAKENE

AB	ABBOTT LABORATORIES	250MG	N18081 001

VALPROIC ACID

AB	PAR PHARMACEUTICAL	250MG¤	N70431 001 FEB 28, 1986

VANCOMYCIN HYDROCHLORIDE (PAGE 3-220)

CAPSULE; ORAL
VANCOCIN HCL

	ELI LILLY	EQ 125MG BASE¤	N50606 001 APR 15, 1986
		EQ 250MG BASE¤	N50606 002 APR 15, 1986

INJECTABLE; INJECTION
VANCOCIN HCL

AP	ELI LILLY	EQ 500MG BASE/VIAL	N60180 001
AP		EQ 500MG BASE/VIAL¤	N62476 001 MAR 15, 1986
		EQ 1GM BASE/VIAL¤	N62476 002 MAR 21, 1986
		EQ 1GM BASE/VIAL¤	N60180 002 MAR 21, 1986

VANCOLED

AP	LEDERLE PARENTERALS	EQ 500MG BASE/VIAL¤	N62682 001 JUL 22, 1986

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION
VERAPAMIL HCL

AP	INTL MEDICATION SYS	2.5MG/ML¤	N70451 001 DEC 16, 1985
AP	LUITPOLD PHARMS	2.5MG/ML¤	N70225 001 NOV 12, 1985
AP		2.5MG/ML¤	N70617 001 NOV 12, 1985
AP	LYPHOMED	2.5MG/ML¤	N70348 001 MAY 01, 1986
AP	QUAD PHARMS	2.5MG/ML¤	N70672 001 MAR 07, 1986

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

TABLET; ORAL
VERAPAMIL HCL

AB	BARR LABORATORIES	80MG¤		N70482 001
			SEP 24, 1986 : SEP 23, 1986	
AB		120MG¤		N70483 001
			SEP 24, 1986 : SEP 23, 1986	
AB	CHELSEA LABORATORIES	80MG¤		N70421 001
			SEP 24, 1986 : SEP 17, 1986	
AB		120MG¤		N70422 001
			SEP 24, 1986 : SEP 17, 1986	
AB	DANBURY PHARMACAL	80MG¤		N70855 001
			SEP 24, 1986 : SEP 23, 1986	
AB		120MG¤		N70856 001
			SEP 24, 1986 : SEP 23, 1986	
AB	PARKE-DAVIS/W-L	80MG¤		N70340 001
			SEP 24, 1986 : AUG 20, 1986	
AB		120MG¤		N70341 001
			SEP 24, 1986 : AUG 20, 1986	
AB	PUREPAC/KALIPHARMA	80MG¤		N71019 001
			SEP 24, 1986 : SEP 23, 1986	
AB		120MG¤		N70468 001
			SEP 24, 1986 : SEP 23, 1986	
AB	WATSON LABS	80MG¤		N70995 001
				OCT 01, 1986
AB		80MG¤		N71366 001
				OCT 01, 1986
AB		120MG¤		N70994 001
				OCT 01, 1986
AB		120MG¤		N71367 001
				OCT 01, 1986

>ADD> TABLET, CONTROLLED RELEASE; ORAL
>ADD> ISOPTIN SR

>ADD>	KNOLL PHARMACEUTICAL	240MG¤	N19152 001
>ADD>			DEC 16, 1986

VINBLASTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION
VELBAN

/ELI LILLY/		/10MG/AMP/	/N12665 001/
AP	ELI LILLY	10MG/VIAL	N12665 001
	VINBLASTINE SULFATE		
AP	LYPHOMED	10MG/VIAL¤	N89011 001
			NOV 18, 1985
AP	QUAD PHARMS	10MG/VIAL¤	N89365 001
			AUG 07, 1986

VINCRISTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION
ONCOVIN

AP	ELI LILLY	1MG/ML	N14103 003
			MAR 07, 1984
	VINCRISTINE SULFATE		
AP	LYPHOMED	1MG/ML¤	N70411 001
			SEP 10, 1986
AP	QUAD PHARMS	1MG/ML¤	N70777 001
			APR 29, 1986
AP		1MG/ML¤	N70778 001
			MAY 01, 1986

WARFARIN SODIUM (PAGE 3-221)

TABLET; ORAL
COUMADIN

/BX/	/DUPONT PHARMS/DUPONT/2.5MG/		/N09218 018/
AB	DUPONT PHARMS/DUPONT	2.5MG	N09218 018
	WARFARIN SODIUM		
AB	COLMED LABORATORIES	2.5MG¤	N88720 001
			AUG 06, 1985

ZINC CHLORIDE (PAGE 3-223)

INJECTABLE; INJECTION
ZINC CHLORIDE IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	EQ 1MG ZINC/ML¤	N18959 001
			JUN 26, 1986

ACETAMINOPHEN (PAGE 3-224)

SUPPOSITORY; RECTAL
ACETAMINOPHEN

>ADD>	SUPPOSITORIA	650MG¤	N70608 001	
>ADD>			DEC 01, 1986	

BACITRACIN; POLYMYXIN B SULFATE (PAGE 3-224)

AEROSOL; TOPICAL
LANABIOTIC

COMBE	500 UNITS/GM; 5,000 UNITS/GM¤	N50598 001	
		SEP 22, 1986	

CHLORHEXIDINE GLUCONATE (PAGE 3-224)

SOLUTION; TOPICAL

CIDA-STAT			
HUNTINGTON LABS	2%¤	N19258 001	
		JUL 22, 1986	
CHG SCRUB			
HUNTINGTON LABS	4%¤	N19258 002	
		JUL 22, 1986	
EXIDINE			
XTTRIUM LABS	2%¤	N19422 001	
		DEC 17, 1985	
	2.5%¤	N19421 001	
		DEC 17, 1985	
STERI-STAT			
MEDICAL SYS RES	4%¤	N70104 001	
		JUL 24, 1986	

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-225)

TABLET, CONTROLLED RELEASED; ORAL
PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE

DORSEY LABS/SANDOZ	12MG;75MG¤	N19613 001	
		JUN 16, 1986	

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-225)

CAPSULE, CONTROLLED RELEASE; ORAL
ISOCLOR

AM CRITICAL CARE/AHS	8MG;120MG¤	N18747 001	
		MAR 06, 1986	

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX (PAGE 3-225)

SYRUP; ORAL
PENNTUSS

PENNWALT PHARM	EQ 4MG MALEATE/5ML; EQ 10MG BASE/5ML	N18928 001	
		AUG 14, 1985	

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-225)

SYRUP; ORAL

BELDIN			
HALSEY DRUG	12.5MG/5ML¤	N89179 001	
		JUN 05, 1986	
DIPHEN			
BAY LABORATORIES	12.5MG/5ML¤	N70118 001	
		OCT 01, 1985	
HYDRAMINE			
NATL PHARM MFG/BARRE	12.5MG/5ML¤	N70205 001	
		JAN 28, 1986	

DOXYLAMINE SUCCINATE (PAGE 3-225)

CAPSULE; ORAL
UNISOM

PFIZER LABS/PFIZER	25MG¤	N19440 001	
		FEB 05, 1986	

EPINEPHRINE (PAGE 3-225)

AEROSOL; INHALATION

BRONKAID MIST			
WINTHROP-BREON/STERL	0.25MG/INH	N16803 001	
EPINEPHRINE MIST			
NATL PHARM MFG/BARRE	0.2MG/INH	N87907 001	
		MAY 23, 1984	
PRIMATENE MIST			
WHITEHALL LABS/AMHO	0.2MG/INH	N16126 001	

EPINEPHRINE BITARTRATE (PAGE 3-225)

AEROSOL; INHALATION

BRONITIN MIST			
WHITEHALL LABS/AMHO	0.3MG/INH	N16126 002	
MEDIHALER EPI			
RIKER LABS/3M	0.3MG/INH	N10374 003	

IBUPROFEN (PAGE 3-225)

TABLET; ORAL

IBUPROFEN			
BARR LABORATORIES	200MG¤		N70493 001
		SEP 24, 1986 :	DEC 24, 1985
	200MG¤		N70908 001
			SEP 26, 1986
	200MG¤		N71462 001
			OCT 02, 1986
CHELSEA LABORATORIES	200MG¤		N70605 001
		SEP 24, 1986 :	MAY 07, 1986
CORD LABORATORIES	200MG¤		N70733 001
		SEP 24, 1986 :	SEP 19, 1986
DANBURY PHARMACAL	200MG¤		N70435 001
		SEP 24, 1986 :	MAR 05, 1986
OHM LABORATORIES	200MG¤		N71163 001
		SEP 24, 1986 :	JUL 15, 1986
>ADD<	200MG¤		N71214 001
>ADD<			DEC 01, 1986
PAR PHARMACEUTICAL	200MG¤		N70481 001
		SEP 24, 1986 :	OCT 18, 1985
PURPEC/KALIPHARMA	200MG¤		N71122 001
			OCT 03, 1986
MEDIPREN			
MCNEIL CONSUMER PROD	200MG¤		N70475 001
		SEP 24, 1986 :	FEB 06, 1986
	200MG¤		N71215 001
		SEP 24, 1986 :	JUN 26, 1986
PROFEN			
PRIVATE FORMULATIONS	200MG¤		N71265 001
			OCT 15, 1986

INSULIN, PURIFIED, HUMAN, SEMISYNTHETIC ; INSULIN SUSPENSION, ISOPHANE, PURIFIED HUMAN (SEMISYNTHETIC) (PAGE 3-226)

INJECTABLE; INJECTION

NOVOLIN 70/30		
SQUIBB/NOVO	30 UNITS/ML;70 UNITS/ML¤	N19441 001
		JUL 11, 1986

INSULIN, PURIFIED PORK (PAGE 3-227)

INJECTABLE; INJECTION

/INSULIN NORDISK QUICK (PORK)/		
VELOSULIN		
NORDISK	100 UNITS/ML	N18193 001

INSULIN SUSPENSION, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION

HUMULIN BR		
ELI LILLY	100 UNITS/ML¤	N19529 001
		APR 28, 1986

INSULIN SUSPENSION, ISOPHANE, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION

HUMULIN N		
ELI LILLY	100 UNITS/ML	N18781 001
		OCT 28, 1982

INSULIN SUSPENSION, ISOPHANE, PURIFIED HUMAN (SEMISYNTHETIC) (PAGE 3-226)

INJECTABLE; INJECTION

INSULATARD NPH HUMAN		
NORDISK USA	100 UNITS/ML¤	N19449 001
		MAY 30, 1986

INSULIN ZINC SUSPENSION, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION

HUMULIN L		
ELI LILLY	100 UNITS/ML¤	N19377 002
		SEP 30, 1985

INSULIN, PURIFIED, HUMAN, SEMISYNTHETIC (PAGE 3-227)

INJECTABLE; INJECTION

VELOSULIN HUMAN		
NORDISK USA	100 UNITS/ML¤	N19450 001
		MAY 30, 1986

OXYMETAZOLINE HYDROCHLORIDE (PAGE 3-228)

SOLUTION/DROPS; OPHTHALMIC

OCUCLEAR		
SCHERING	0.025%¤	N18471 001
		MAY 30, 1986

POVIDONE-IODINE (PAGE 3-228)

SPONGE; TOPICAL

POVIDONE-IODINE		
PARKE-DAVIS/DESERET	20%¤	N19240 001
		NOV 29, 1985

PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-228)

CAPSULE, CONTROLLED RELEASE; ORAL

/SUDAFED S.A./		
SUDAFED 12 HOUR		

PYRITHIONE ZINC (PAGE 3-228)

LOTION; TOPICAL
HEAD & SHOULDERS CONDITIONER

PROCTER AND GAMBLE	0.3%	N19412 001 MAR 10, 1986
	0.3%	N19412 002 MAR 10, 1986
	0.3%	N19412 003 MAR 10, 1986
	0.3%	N19412 004 MAR 10, 1986

SODIUM MONOFLUOROPHOSPHATE (PAGE 3-229)

GEL; DENTAL
EXTRA-STRENGTH AIM

LEVER BROTHERS	1.2%	N19518 001 AUG 06, 1986

NO SEPTEMBER 1985 - DECEMBER 1986 APPROVALS

C. APPENDICES

1. Orphan Drug Products with Exclusive Approval

2. List of Drug Products Which Must Demonstrate *in vivo* Bioavailability Only if Product Fails to Achieve Adequate Dissolution

3. Biopharmaceutic Guidance Availability List

4. ANDA Suitability Petitions

5. Exclusivity Terms

6. Prescription and OTC Drug Product Patent and Exclusivity Data

APPENDIX 1

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

Section 526 of the Federal Food, Drug, and Cosmetic Act contains provisions whereby FDA may designate a sponsor's drug, antibiotic, or biological product as a "designated orphan drug". Section 527 of the Act establishes a process whereby a sponsor may receive seven years of exclusive approval status if that sponsor is the first to achieve new drug, antibiotic, or biological product approval for a designated orphan drug for the designated indication(s). The exclusive approval may be revoked by written consent of the sponsor or by FDA action after finding that the sponsor holding exclusive approval cannot assure the availability of sufficient quantities of the drug to meet the needs of patients with the designated orphan indication(s).

Orphan Drug exclusive approval status (coded ODE) applies only to the approved or licensed indication(s) for which orphan drug designation has been granted pursuant to Section 526 of the Act.

For the following drug products with orphan drug exclusive approval status, the sponsor has seven years of exclusive approval for the approved indication beginning on the date of NDA, antibiotic application, or biological license approval for the drug. No subsequent sponsor may receive approval of an NDA, biological license, paper NDA, antibiotic application, ANDA, or abbreviated antibiotic application during the seven year period for the drug and indication(s) for which a person maintains ODE status unless the exclusive approval has been revoked as described above or the subsequent sponsor has obtained written consent from the sponsor who has received exclusive approval.

Biological products, antibiotics, and drugs that have been approved under section 505 or 507 of the Act or under section 351 of the Public Health Service Act for marketing and have been given orphan drug exclusive approval will be noted by the abbreviation ODE in the Patent and Exclusivity Data Appendix. Drug products that have received the written permission of the sponsor that has orphan drug exclusive approval to be approved under section 527(b)(2) of the Act are also noted by the abbreviation ODE in the Patent and Exclusivity Data Appendix. These drug products do not have any exclusive approval rights of their own, but can be marketed because of the consent given by the sponsor that has exclusive approval. These products are marked by an (*) next to the applicant's name.

APPENDIX 1

BIOLOGICAL PRODUCTS

Active Ingred.(s) Strength	Trade Name Dosage Form; Route	Applicant	License Number Approval Date	Exclusivity Exp.Date
Hemin 313mg/amp	Panhematin Injectable; Injection	Abbott Laboratories	43 Jul 20, 1983	ODE Jul 20, 1990
Digoxin Immune Fab (OVINE)	Digibind Injectable; Injection	Burroughs Wellcome	129 Apr 22, 1986	ODE Apr 22, 1993

APPENDIX 1

DRUG PRODUCTS

Active Ingred.(s) Strength(s)	Trade Name Dosage Form; Route	Applicant	Appl. Prod. Approval Date	Exclusivity Exp. Date
Chenodiol 250mg	Chenix Tablet; Oral	Rowell Laboratories	18513 002 Jul 28, 1983	ODE Jul 28, 1990
Cromolyn Sodium 4%	Opticrom Solution/Drops; Ophthalmic	Fisons	18155 001 Oct 3, 1984	ODE Oct 3, 1991
Carnitine, L- 330mg	L-Carnitine Tablet; Oral	Sigma-Tau	18948 001 Dec 27, 1985	ODE Dec 27, 1992
Carnitine, L- 1gm/10ml	Vitacarn Solution; Oral	Kendall McGaw Labs*	19257 001 Apr 10, 1986	
Clofazimine 50mg	Lampreme Capsule; Oral	Geigy/Ciba-Geigy	19500 002 Dec 15, 1986	ODE Dec 15, 1993
Clofazimine 100mg	Lampreme Capsule; Oral	Geigy/Ciba-Geigy	19500 001 Dec 15, 1986	ODE Dec 15, 1993

(continued)

*Refer to Appendix I narrative

APPENDIX 1

DRUG PRODUCTS

(continued)

Active Ingred.(s) Strength(s)	Trade Name Dosage Form; Route	Applicant	Appl. Prod. Approval Date	Exclusivity Exp. Date
Naltrexone Hydrochloride 50mg	Trexan Tablet; Oral	Dupont Pharms	18932 001 Nov 20, 1984	ODE Nov 20, 1991
Monooctanoin 100%	Moctanin Liquid; Perfusion Biliary	Ascot Hosp Pharms	19368 001 Oct 29, 1985	ODE Oct 29, 1992
Pentamidine Isethionate 300mg/ml	Pentam 300 Injectable; Injection	LyphoMed	19264 001 Oct 16, 1984	ODE Oct 16, 1991
Potassium Citrate 5meq	Urocit-K Tablet; Oral	Univ of Tx Hlth Sci Ctr	19071 001 Aug 30, 1985	ODE Aug 30, 1992
Somatrem 5mg/vial	Protropin Injectable; Injection	Genentech	19107 001 Oct 17, 1985	ODE Oct 17, 1992

(continued)

APPENDIX 1

DRUG PRODUCTS

(continued)

Active Ingred.(s) Strength(s)	Trade Name Dosage Form; Route	Applicant	Appl. Prod. Approval Date	Exclusivity Exp. Date
Trientine Hydrochloride 250mg	Cuprid Capsule; Oral	Merck Sharp and Dohme Res Labs	19194 001 Nov 8, 1985	ODE Nov 08, 1992
Tranexamic Acid 500mg	Cyklokapron Tablet; Oral	Kabivitrum	19280 001 Dec 30, 1986	ODE Dec 30, 1993
Tranexamic Acid 100mg/ml	Cyklokapron Injectable; Injection	Kabivitrum	19281 001 Dec 30, 1986	ODE Dec 30, 1993

APPENDIX 2

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

Acetaminophen; Aspirin; Butalbital
Capsule or Tablet; Oral
160-165mg; 160-165mg; 50mg

Acetaminophen; Aspirin; Butalbital
Capsule or Tablet; Oral
325mg; 325mg; 50mg

Acetaminophen; Aspirin; Butalbital; Caffeine
Capsule or Tablet; Oral
160-165mg; 160-165mg; 50mg; 40mg

Acetaminophen; Aspirin; Butalbital; Caffeine
Capsule or Tablet; Oral
325mg; 325mg; 50mg; 40mg

Acetaminophen; Butalbital
Capsule or Tablet; Oral
325mg; 50mg
650mg; 50mg

Acetaminophen; Butalbital; Caffeine
Capsule or Tablet; Oral
325mg; 50mg; 40mg
650mg; 50mg; 40mg

Aminophylline
Tablet; Oral
100mg
200mg

Aspirin; Butalbital
Capsule or Tablet; Oral
325mg; 50mg
650mg; 50mg

Aspirin; Butalbital; Caffeine
Capsule or Tablet; Oral
325mg; 50mg; 40mg;
650mg; 50mg; 40mg;

Aspirin; Caffeine; Carisoprodol
Tablet; Oral
160mg; 32mg; 200mg

Aspirin; Caffeine; Carisoprodol; Codeine Phosphate
Tablet; Oral
160mg; 32mg; 200mg; 16mg

Aspirin; Carisoprodol
Tablet; Oral
325mg; 200mg

Aspirin; Carisoprodol; Codeine Phosphate
Tablet; Oral
325mg; 200mg; 10mg

Aspirin; Meprobamate
Tablet; Oral
325mg; 200mg

Aspirin; Methocarbamol
Tablet; Oral
325mg; 200mg

Chlorothiazide
Tablet; Oral
250mg

Estrogens, Conjugated; Meprobamate
Tablet; Oral
0.4mg; 200mg
0.4mg; 400mg

Hydroxyzine Hydrochloride
Tablet; Oral
10mg
25mg
50mg
100mg

APPENDIX 3

BIOPHARMACEUTIC GUIDANCE AVAILABILITY LIST

The following is a list of guidances available for in vivo bioequivalence studies and in vitro dissolution testing available from the Division of Bioequivalence, HFN-250, Room 17B-06, 5600 Fishers Lane, Rockville, MD 20857. Comments and suggestions concerning these guidances are encouraged and should be sent to the Division of Bioequivalence.

Name of Drug	Date	Revised Date
Acetohexamide	Nov 15, 1985	
Allopurinol	Jul 15, 1985	
Amiloride Hydrochloride	Mar 29, 1985	
Aminophylline Suppositories	Jul 05, 1983	
Amitriptyline Hydrochloride	Jul 05, 1983	
Anticholinergic Drugs (Controlled Release)	Nov 07, 1980	
Baclofen	May 05, 1986	
Carbamazepine	Dec 05, 1984	Aug 04, 1986
Cefadroxil	Oct 07, 1986	
Cephradine (Capsule and Suspension)	Sep 10, 1986	
Cephalexin (Tablet and Capsule)	Aug 13, 1986	Oct 27, 1986
*Cholestyramine Resin	Dec 24, 1986	
Chlordiazepoxide Hydrochloride	Jul 05, 1983	
Chlorpropamide	Jul 05, 1983	
Chlorthalidone	Jul 05, 1983	
Clofibrate	Apr 07, 1986	
Clonidine Hydrochloride	Dec 05, 1984	
Clorazepate Dipotassium	Mar 10, 1986	
*Conjugated Estrogen (Tablet)	Dec 17, 1986	

(continued)

*New Addition

APPENDIX 3

(continued)

Name of Drug	Date	Revised Date
Diazepam (revised)	Jul 08, 1985	
Dicyclomine Hydrochloride	Aug 10, 1984	
Dipyridamole	Jul 05, 1983	
Disopyramide Phosphate	Jul 09, 1985	
Dissolution Testing (General)	Apr 19, 1985	
Doxepin Hydrochloride	Apr 02, 1985	Oct 09, 1986
Erythromycin	Apr 05, 1977	
Flurazepam	Oct 15, 1985	
Hydrochlorothiazide	Jul 25, 1983	
Hydroxyzine Hydrochloride (Dissolution Only)	Jan 27, 1981	
Hydroxyzine Pamoate	Jul 26, 1983	
Indomethacin	Apr 06, 1985	
Isosorbide Dinitrate	Jun 04, 1985	
Isosorbide Dinitrate (Controlled Release Products)	Sep 19, 1985	
Lorazepam	Dec 03, 1984	
Meclofenamate Sodium	Nov 12, 1986	
*Medroxyprogesterone Acetate (Tablet)	Dec 24, 1986	
Methylprednisolone	Jun 12, 1986	
Methyltestosterone	Nov 16, 1979	
Metoclopramide	Dec 27, 1984	
Minoxidil	Apr 02, 1986	
Nitrofurantoin (Macrocrystalline)	Oct 29, 1985	
*Nitroglycerin (Ointment)	Dec 17, 1986	

(continued)

*New Addition

APPENDIX 3

(continued)

Name of Drug	Date	Revised Date
Phentermine Hydrochloride (Dissolution)	Nov 21, 1980	
Phentermine Hydrochloride (Slow Dissolving; Dissolution)	Nov 21, 1980	
Phenylbutazone & Oxyphenbutazone	Jul 26, 1983	
Prednisone (Dissolution Only)	Jul 10, 1985	
Probenecid	Jul 26, 1983	
Procainamide	Jul 25, 1983	
Propranolol	May 19, 1984	
Propylthiouracil	Aug 13, 1986	
Quinidine Gluconate (Controlled Release)	Jun 15, 1981	
Spironolactone	Jul 25, 1983	
Sulfinpyrazone	Jul 15, 1983	
Temazepam	Aug 1985	
Theophylline (Controlled Release)	Apr 1984	
Theophylline (Immediate Release)	Nov 02, 1983	
Tolazamide	Aug 22, 1984	
Tolbutamide	Jan 1982	
Trazodone	Nov 15, 1985	Apr 30, 1986
Trimipramine	Nov 03, 1986	
Verapamil	Jul 1985	

APPENDIX 4

ANDA SUITABILITY PETITIONS

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 (List I., Petitions Approved) and (2) is not suitable for submission as an ANDA (List II., 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.

I. Petitions Approved

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Capsule; Oral	500mg 30mg	84 P-0228/CP	McNeil Pharm	New Dosage Form New Strength	Approved Jun 02, 1986
Acetaminophen; Codeine Phosphate Capsule; Oral	500mg 60mg	84 P-0228/CP	McNeil Pharm	New Dosage Form New Strength	Approved Jun 02, 1986
Acetaminophen; Codeine Phosphate Capsule; Oral	650mg 15mg	86 P-0200/CP	Mikart, Inc	New Strength New Dosage Form	Approved Oct 3, 1986
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	300mg 30mg	85 P-0543/CP	Softan	New Dosage Form	Approved Mar 18, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	500mg 7.5mg	85 P-0543/ CP0002	Softan	New Dosage Form New Strength	Approved Mar 19, 1986
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	500mg 15mg	85 P-0543/ CP0002	Softan	New Dosage Form New Strength	Approved Mar 19, 1986
Acetaminophen; Codeine Phosphate Elixir; Oral	160mg/5ml 6mg/5ml	86 P-0133/CP	Kleinfeld, Kaplan and Becker	New Strength	Approved May 21, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 15mg	86 P-0161/CP	Roxane Laboratories	New Strength	Approved May 8, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 30mg	86 P-0161/CP	Roxane Laboratories	New Strength	Approved May 8, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 60mg	86 P-0161/CP	Roxane Laboratories	New Strength	Approved May 8, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	650mg 15mg	86 P-0200/CP	Mikart, Inc	New Strength	Approved Oct 3, 1986
Acetaminophen; Hydrocodone Bitartrate Solution; Oral	500mg/15ml 5mg/15ml	84 P-0391/CP	UAD Laboratories	New Dosage Form	Approved Jul 2, 1985
Acetaminophen; Oxycodone Hydrochloride Solution; Oral	325mg/5ml 5mg/5ml	85 P-0085/CP	Roxane Laboratories	New Dosage Form	Approved Aug 23, 1985
Acetaminophen; Oxycodone Hydrochloride Soft Gelatin Capsule; Oral	500mg 5mg	85 P-0543/ CP0003	Softan	New Dosage Form	Approved Mar 18, 1986
Acetaminophen; Propoxyphene Hydrochloride Soft Gelatin Capsule; Oral	500mg 32mg	85 P-0581/CP	Softan	New Dosage Form New Strength	Approved Mar 18, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen Suppository; Rectal	80mg	85 P-0403/CP	Upsher-Smith Labs	New Dosage Form (Pediatric)	Approved Oct 16, 1985
Aminocaproic Acid Injectable; Injection	500mg/ml (10ml/vial)	85 P-0308/CP	Abbott Laboratories	New Strength	Approved Feb 12, 1986
Aminophylline Injectable; Injection	10mg/ml (10ml/vial)	85 P-0459/CP	Abbott Laboratories	New Strength	Approved Feb 12, 1986
Aminophylline Injectable; Injection	50mg/ml (20ml/vial)	85 P-0459/CP	Abbott Laboratories	New Strength	Approved Feb 12, 1986
Aspirin; Caffeine; Dihydrocodeine Bitartrate Tablet; Oral	356.4mg 30mg 16mg	86 P-0359/CP	Central Pharms	New Dosage Form	Approved Sep 29, 1986
Azatadine Maleate; Phenylpropanolamine Hydrochloride Sustained Release Capsule; Oral	1mg 75mg	85 P-0492/CP	SK&F Laboratories	New Combination New Dosage Form	Approved Jan 28, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Benztropine Mesylate Syrup; Oral	0.5mg/5ml	85 P-0423/CP	RIM Consulting	New Dosage Form	Approved Oct 16, 1985
Bretylium Tosylate Injectable; Injection	100mg/ml	86 P-0157/CP	Lyphomed	New Strength	Approved May 8, 1986
Brompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	12mg 120mg	85 P-0095/CP	UAD Laboratories	New Combination New Dosage Form	Approved Dec 13, 1985
Cholestyramine Tablet, Chewable; Oral	Eq 4gm Resin	86 P-0123/CP	Parke-Davis Labs/W-L	New Dosage Form	Approved Jun 20, 1986
Chlorpheniramine Maleate; Phenylpropanolamine Hydrochloride Controlled-release Capsule; Oral	10mg 75mg	85 P-0149/CP	Dura Pharmaceuticals	New Strength	Approved Dec 13, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Chlorhexidine Gluconate Solution; Topical	1.5%	84 P-0417/CP	Parke-Davis	New Strength	Approved Sep 18, 1985
Cisplatin Injectable, Injection	100mg/vial	86 P-0395/CP	Ben Venue Labs	New Strength	Approved Dec 8, 1986
Codeine Phosphate; Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Syrup; Oral	10mg/5ml 1mg/5ml 12.5mg/5ml	85 P-0269/CP	Bock Pharmacal	New Combination	Approved Dec 6, 1985
Cytarabine Injectable; Injection	20mg/ml (5ml/vial)	86 P-0130/CP	Quad Pharms	New Dosage Form	Approved Aug 21, 1986
Cytarabine Injectable; Injection	20mg/ml (25ml/vial)	86 P-0130/CP	Quad Pharms	New Dosage Form	Approved Aug 21, 1986
Dacarbazine Injectable; Injection	500mg/vial	86 P-0300/CP	Quad Pharms	New Strength	Approved Aug 15, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Time Release Capsule; Oral	6mg 75mg	85 P-0238/ CP0002	Bock Pharmacal	New Combination	Approved Dec 13, 1985
Dexbrompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/CP	Central Pharms	New Combination New Dosage Form	Approved Dec 13, 1985
Dexbrompheniramine Maleate; Pseudoephedrine Sulfate Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/ CP0002	Central Pharms	New Dosage Form	Approved Jan 22, 1986
Diazepam Solution; Oral	5mg/5ml	85 P-0090/CP	Roxane Laboratories	New Dosage Form	Approved Sep 19, 1985
Diazepam Syrup; Oral	2mg/5ml	85 P-0499/CP	Carolina Med Prods	New Dosage Form	Approved Feb 28, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Diazepam Intensol Solution (Concentrate); Oral	5mg/ml	85 P-0566/CP	Roxane Laboratories	New Dosage Form	Approved Mar 18, 1986
Diphenhydramine Hydrochloride Concentrate; Oral	50mg/ml	84 P-0174/CP	Roxane Laboratories	New Strength	Approved Sep 11, 1985
Disopyramide Phosphate Tablet, Controlled Release; Oral	200mg 300mg	84 N-0116/CP	Biocraft Labs	New Dosage Form New Strength	Approved Jun 03, 1986
Disulfiram Suspension; Oral	500mg/30ml	85 P-0215/CP	Paddock Laboratories	New Dosage Form	Approved Oct 8, 1985
Estradiol Tablet; Oral	0.5mg	84 P-0308/CP	Key Pharmaceuticals	New Strength	Approved Mar 24, 1986
Floxuridine Injectable; Injection	500mg/5ml	86 P-0242/CP	Quad Pharms	New Dosage Form	Approved Aug 15, 1986
Fluorouracil Injectable; Injection	25mg/ml	85 P-0208/CP	Intl Pharm Prods	New Strength	Approved Oct 8, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Fluorouracil Injectable; Injection	50mg/ml (100ml/vial)	85 P-0221/CP	LyphoMed	New Strength	Approved Feb 18, 1986
Fluorouracil Injectable; Injection	50mg/ml (20ml/vial)	86 P-0080/CP	Ben Venue Labs	New Strength	Approved Apr 2, 1986
Flurazepam Concentrate; Oral	30mg/ml	85 P-0081/CP	Roxane Laboratories	New Dosage Form	Approved Jul 10, 1985
Flurazepam Hydrochloride Solution; Oral	15mg/5ml	85 P-0091/CP	Roxane Laboratories	New Dosage Form	Approved Oct 25, 1985
Furosemide Solution; Oral	40mg/5ml	85 P-0106/ CP0002	Roxane Laboratories	New Strength	Approved Sep 19, 1985
Furosemide Concentrate; Oral	80mg/ml	85 P-0106/CP	Roxane Laboratories	New Strength	Approved Sep 19, 1985
Glucagon Injectable; Injection	Eq 2mg Base/Amp	86 P-0411/CP	King and Spaulding	New Strength	Approved Oct 30, 1986
Haloperidol Solution; Oral	2mg/5ml	85 P-0076/ CP0002	Roxane Laboratories	New Strength	Approved Mar 26, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Haloperidol Lactate Intensol Concentrate; Oral	Eq 5mg Base/ml	85 P-0076/CP	Roxane Laboratories	New Strength	Approved Dec 8, 1986
Haloperidol Solution; Oral	5mg/5ml	85 P-0080/CP	Roxane Laboratories	New Strength	Approved Sep 19, 1985
Hydralazine Hydrochloride Solution; Oral	25mg/5ml	85 P-0074/CP	Roxane Laboratories	New Dosage Form	Approved Jul 3, 1985
Hydrochlorothiazide; Triamterene Capsule; Oral	50mg 75mg	86 P-0427/CP	Par Pharmaceutical	New Dosage Form	Approved Dec 11, 1986
Ibuprofen Capsule; Oral	200mg	84 P-0383/CP	Sterling Drug	New Dosage Form	Approved Jun 25, 1985
Ibuprofen Soft Gelatin Capsule; Oral	300mg 400mg 600mg	85 P-0563/CP	Softan	New Dosage Form	Approved Mar 19, 1986
Indomethacin Suspension; Oral	25mg/5ml	85 P-0077/ CP0002	Roxane Laboratories	New Dosage Form	Approved Jul 19, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Isoniazid Concentrate; Oral	50mg/ml	85 P-0468/CP	Carolina Med Prods	New Strength	Approved Dec 13, 1985
Ketoconazole Suspension; Oral	20mg/ml	85 P-0147/CP	Janssen Pharma	New Dosage Form	Approved Sep 27, 1985
Leucovorin Calcium Tablet; Oral	15mg	85 P-0487/CP	Lederle Labs/AM Cyan	New Strength	Approved Jan 28, 1986
Lorazepam Oral; Solution	1mg/5ml	86 P-0292/CP	Roxane Laboratories	New Dosage Form	Approved Oct 15, 1986
Lorazepam Solution (Concentrate); Oral	2mg/ml	86 P-0291/CP	Roxane Laboratories	New Dosage Form	Approved Oct 15, 1986
Meperidine Hydrochloride Concentrate; Oral	100mg/ml	84 P-0175/CP	Roxane Laboratories	New Strength	Approved Jun 7, 1985
Metaproterenol Sulfate Solution; Inhalation	10mg/2.5ml	85 P-0509/CP	Armour Pharm	New Strength	Approved Feb 28, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Metaproterenol Sulfate Solution; Inhalation	10mg/3ml	85 P-0429/ CP0002	Dey Laboratories	New Strength	Approved Feb 28, 1986
Metaproterenol Sulfate Solution; Inhalation	15mg/3ml	85 P-0429/CP	Dey Laboratories	New Strength	Approved Feb 28, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml (20ml/vial)	86 P-0036/CP	AM Critical Care/AHS	New Strength	Approved Mar 18, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml (50ml/vial)	85 P-0545/CP	Lyphomed	New Strength	Approved Feb 28, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml (50ml/vial)	85 P-0540/CP	Quad Pharms	New Strength	Approved Feb 28, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml (100ml/vial)	85 P-0540/CP	Quad Pharms	New Strength	Approved Feb 28, 1986
Methyldopate Hydrochloride Injectable; Injection	50mg/ml (10ml/vial)	85 P-0404/CP	AM Critical Care/AHS	New Strength	Approved Oct 25, 1985
Methyltestosterone Capsule; Oral	25mg	85 P-0067/CP	Star Pharmaceuticals	New Dosage Form	Approved Aug 23, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Miconazole Nitrate Cream; Vaginal	4%	84 P-0398/CP	Ortho Pharmaceutical	New Strength	Approved Mar 31, 1986
Naloxone Hydrochloride Injectable; Injection	1mg/ml (5ml/vial)	86 P-0079/CP	AM Critical Care/AHS	New Strength	Approved May 7, 1986
Naloxone Hydrochloride Injectable; Injection	1mg/ml (10ml/vial)	86 P-0079/CP	AM Critical Care/AHS	New Strength	Approved May 7, 1986
Nitroglycerin Injectable; Injection	5mg/ml	86 P-0025/CP	Lyphomed	New Strength	Approved Apr 1, 1986
Nitroglycerin Injectable; Injection	10mg/ml	85 P-0134/CP	Marion Laboratories	New Strength	Approved Sep 19, 1985
Nitroglycerin in 5% Dextrose Injectable; Injection	10mg/100ml (500ml Container)	86 P-0099/CP	Abbott Laboratories	New Strength	Approved Apr 1, 1986
Nitroglycerin in 5% Dextrose Injectable; Injection	20mg/100ml (250ml Container)	86 P-0099/ CP0002	Abbott Laboratories	New Strength	Approved Apr 1, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Nitroglycerin in 5% Dextrose Injectable; Injection	40mg/100ml (250ml and 500ml Containers)	86 P-0099/ CP0003	Abbott Laboratories	New Strength	Approved Apr 1, 1986
Prednisolone Syrup; Oral	5mg/5ml	86 P-0399/CP	Muro Pharmaceutical	New Strength	Approved Dec 8, 1986
Probucol Tablet; Oral	500mg	85 P-0337/CP	Merrell Dow/Dow Chem	New Strength	Approved Oct 25, 1985
Procainamide Hydrochloride Tablet; Oral	375mg	85 P-0125/CP	Key Pharmaceuticals	New Strength	Approved Sep 19, 1985
Propranolol Hydrochloride Capsule; Oral	10mg 20mg 40mg 60mg 80mg 90mg	86 P-0045/CP	Nutripharm Labs	New Dosage Form	Approved Mar 19, 1986
Propranolol Hydrochloride Solution; Oral	40mg/5ml	85 P-0073/CP	Roxane Laborataories	New Dosage Form	Approved Jul 8, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Propranolol Hydrochloride Concentrate; Oral	80mg/ml	85 P-0073/ CP0002	Roxane Laboratories	New Dosage Form	Approved Jul 19, 1985
Propranolol Hydrochloride Solution; Oral	20mg/5ml	85 P-0073/ CP0003	Roxane Laboratories	New Dosage Form	Approved Sep 24, 1985
Propranolol Hydrochloride Tablet, Constant-Release; Oral	160mg	85 P-0129/CP	Verex Laboratories	New Dosage Form	Approved Sep 25, 1985
Propranolol Hydrochloride Tablet, Controlled Release; Oral	80mg 120mg 160mg	85 P-0197/CP	Forest Laboratories	New Dosage Form	Approved Sep 27, 1985
Pyridostigmine Bromide Tablet; Oral	30mg	85 P-0412/CP	Kali-Duphar Labs	New Strength	Approved Jan 22, 1986
Ritodrine Hydrochloride in Dextrose 5% Injectable; Injection	30mg/100ml (500ml Container)	86 P-0100/CP	Abbott Laboratories	New Strength	Approved May 7, 1986
Scopolamine Transdermal System/24 Hour Film, Controlled Release; Percutaneous	1mg	85 P-0168/CP	Ciba Consumer Pharms	New Strength (Dosing Interval)	Approved Sep 27, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Spironolactone Syrup; Oral	25mg/5ml	85 P-0510/CP	Carolina Med Prods	New Dosage Form	Approved Jan 22, 1986
Spironolactone Oral; Injection	25mg/5ml	86 P-0055/CP	Carolina Med Prods	New Dosage Form	Approved Mar 28, 1986
Theophylline Capsule; Oral	150mg 300mg	85 P-0175/CP	Mead Johnson/B-M	New Strength	Approved Oct 8, 1985
Theophylline Tablet, Controlled-release; Oral	600mg	85 P-0580/CP	Purdue Frederick	New Strength	Approved Oct 15, 1986
Thiothixene Hydrochloride Solution; Oral	5mg/5ml	86 P-0178/CP	Ellis Pharmaceutical	New Strength	Approved Jun 04, 1986
Triamcinolone Acetonide Cream; Topical	0.05%	86 P-0360/CP	Carolina Med Prods	New Strength	Approved Oct 15, 1986
Triamcinolone Acetonide Ointment; Topical	0.05%	86 P-0360/CP	Carolina Med Prods	New Strength	Approved Oct 15, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Vinblastine Sulfate Injectable; Injection	1mg/ml	86 P-0056/CP	Quad Pharms	New Dosage Form	Approved Mar 28, 1986
Vincristine Sulfate Injectable; Injection	2mg/vial	85 P-0016/CP	Bristol Labs/B-M	New Dosage Form	Approved Nov 8, 1985
Xenon XE 133 Gas; Inhalation	150mCi/vial 250mCi/vial	86 P-0041/CP	Medi Nuclear Corp, Inc	New Strength	Approved Oct 15, 1986

APPENDIX 4

II. Petitions Denied

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	650mg 10mg	85 P-0015/CP	Applied Labs	New Strength	Denied Nov 7, 1985
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	750mg 7.5mg	85 P-0169/CP	Knoll Pharmaceutical	New Strength	Denied Nov 7, 1985
Aminocaproic Acid Injectable; Injection	500mg/ml	85 P-0064/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Aminophylline Injectable; Injection	10mg/ml	85 P-0066/CP	Abbott Laboratories	New Strength	Denied May 3, 1985
Aminophylline Injectable; Injection	50mg/ml	85 P-0066/CP	Abbott Laboratories	New Strength	Denied May 3, 1985
5-Aminosalicylic Acid Suppository; Rectal	500mg	84 P-0425/CP	Reid-Rowell	New Ingredient	Denied Jun 05, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Aspirin; Chlorzoxazone Tablet; Oral	325mg 250mg	85 P-0071/CP	McNeil Pharm	New Combination	Denied Sep 3, 1985
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 7.5mg	85 P-0101/CP	Sandoz Pharms/Sandoz	New Combination	Denied Sep 11, 1985
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 15mg	85 P-0101/CP	Sandoz Pharms/Sandoz	New Combination	Denied Sep 11, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 30mg	85 P-0101/CP	Sandoz Pharms/Sandoz	New Combination	Denied Sep 11, 1985
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 60mg	85 P-0101/ CP0002	Sandoz Pharms/Sandoz	New Combination	Denied Sep 11, 1985
Benzoyl Metronidazole Suspension; Injection	200mg/5ml	85 P-0258/CP	Apkon Laboratories	New Ester New Ingredient	Denied Mar 19, 1986
Betamethasone Dipropionate Miconazole Nitrate Cream; Topical	0.05% 2%	85 P-0271/CP	Ortho Pharmaceutical	New Combination	Denied Apr 18, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Bretylium Tosylate Injectable; Injection	2mg/ml	85 P-0063/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Bretylium Tosylate Injectable; Injection	4mg/ml	85 P-0063/ CP0002	Abbott Laboratories	New Strength	Denied May 29, 1985
Bretylium Tosylate Injectable; Injection	8mg/ml	85 P-0063/ CP0003	Abbott Laboratories	New Strength	Denied May 29, 1985
Bretylium Tosylate Injectable; Injection	10mg/ml	85 P-0063/ CP0004	Abbott Laboratories	New Strength	Denied May 29, 1985
Caffeine; Ergotamine Tartrate; Pentobarbital Tablet; Oral	100mg 1mg 30mg	85 P-0433/CP	Sandoz Pharms/Sandoz	New Combination	Denied Nov 8, 1985
Caffeine; Ergotamine Tartrate; Pentobarbital Sodium Suppository; Rectal	200mg 2mg 60mg	85 P-0433/ CP0002	Sandoz Pharms/Sandoz	New Combination	Denied Nov 8, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Cholecalciferol Capsule; Oral	1.25mg	84 P-0161/CP	Pharmacaps	New Active Ingredient	Denied Feb 13, 1986
Codeine Phosphate; Ibuprofen Capsule; Oral	30mg 200mg	84 P-0388/CP	McNeil Pharm	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Capsule; Oral	60mg 200mg	84 P-0388/CP	McNeil Pharm	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Tablet; Oral	30mg 200mg	84 P-0388/CP	McNeil Pharm	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Tablet; Oral	60mg 200mg	84 P-0388/CP	McNeil Pharm	New Combination	Denied Sep 16, 1985
Choline Magnesium Trisalicylate Codeine Phosphate Tablet; Oral	500mg 30mg	85 P-0142/CP	Purdue Frederick	New Combination	Denied Jul 21, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Choline Magnesium Trisalicylate; Codeine Phosphate Tablet; Oral	500mg 60mg	85 P-0142/CP	Purdue Frederick	New Combination	Denied Jul 21, 1986
Dextromethorphan Hydrobromide Tablet, Controlled Release; Oral	60mg	85 P-0135/CP	Ciba Consumer Pharms	New Salt New Ingredient	Denied Jul 17, 1986
Diatrizoate Meglumine; Lidocaine Hydrochloride Injectable; Injection	60% 1.5mg/ml	84 P-0325/CP	Cook Imaging	New Combination	Denied Sep 3, 1985
Diazepam Intensol Concentrate; Oral	10mg/ml	85 P-0075/CP	Roxane Laboratories	New Dosage Form	Denied Sep 24, 1985
Tri-Phasic Contraceptive Tablet; Oral(21 and 28 days) Ethinyl Estradiol Norethindrone Ethinyl Estradiol Norethindrone Ethinyl Estradiol Norethindrone	 0.05mg 0.5mg 0.05mg 0.75mg 0.05mg 1.0mg	84 P-0443/CP	Ortho Pharmaceutical	New Strength (Dose Schedule)	Denied Sep 3, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Fluphenazine Hydrochloride Injectable; Injection	5mg/ml	85 P-0019/CP	ER Squibb and Sons	New Strength	Denied Oct 25, 1985
Heparin Sodium Injectable; Injection	2000 Units/ml	85 P-0065/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Heparin Sodium Injectable; Injection	4000 Units/ml	85 P-0065/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release; Oral	50mg 80mg 75mg	85 P-0571/CP	Ayerst Labs/AMHO	New Combination	Denied May 16, 1986
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release; Oral	50mg 120mg 75mg	85 P-0571/CP	Ayerst Labs/AMHO	New Combination	Denied May 16, 1986
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release; Oral	50mg 160mg 75mg	85 P-0571/CP	Ayerst Labs/AMHO	New Combination	Denied May 16, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Hydrocortisone Acetate Suppository; Rectal	1%	85 P-0088/CP	Parke-Davis Labs/W-L	New Dosage Form New Route of Administration New Strength New Ingredient	Denied Sep 16, 1986
Ibuprofen; Oxycodone Hydrochloride Capsule; Oral	200mg 5mg	85 P-0141/CP	Dupont Pharms/Dupont	New Combination	Denied Sep 27, 1985
Ibuprofen; Oxycodone Hydrochloride Tablet; Oral	200mg 5mg	85 P-0141/CP	Dupont Pharms/Dupont	New Combination	Denied Sep 27, 1985
Indomethacin Tablet; Oral	25mg	85 P-0025/CP	Verex Laboratories	New Dosage Form	Denied Mar 31, 1986
Indomethacin Tablet; Oral	50mg	85 P-0025/CP	Verex Laboratories	New Dosage Form	Denied Mar 31, 1986
Indomethacin Intensol Solution (Concentrate); Oral	50mg/ml	85 P-0077/CP	Roxane Laboratories	New Dosage Form New Strength	Denied Apr 7, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Indomethacin Tablet, Constant Release; Oral	75mg	85 P-0026/CP	Verex Laboratories	New Dosage Form	Denied Sep 16, 1985
Indomethacin Tablet, Controlled Release; Oral	75mg	85 P-0180/CP	Forest Laboratories	New Dosage Form	Denied Apr 7, 1986
Methocarbamol; Acetaminophen Tablet; Oral	400mg 325mg	85 P-0102/CP	McNeil Pharm	New Combination	Denied Jun 24, 1986
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml (50ml/vial)	86 P-0015/CP	Intl Medication Sys	New Strength	Denied Apr 25, 1986
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml (75ml/vial)	86 P-0015/CP	Intl Medication Sys	New Strength	Denied Apr 25, 1986
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml (100ml/vial)	86 P-0015/CP	Intl Medication Sys	New Strength	Denied Apr 25, 1986
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0062/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0457/CP	Abbott Laboratories	New Strength	Denied Apr 18, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0062/ CP0002	Abbott Laboratories	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0457/ CP0002	Abbott Laboratories	New Strength	Denied Apr 18, 1986
Metronidazole Sponge; Vaginal	50-125mg/ Sponge	85 P-0117/CP	VLI	New Dosage Form	Denied Oct 8, 1985
Nitroglycerin Film, Controlled Release; Percutaneous	None Given	84 P-0302/CP	Key Pharmaceuticals	New Dosage Form (New Matrix)	Denied Jul 29, 1985
Phenylephrine Hydrochloride; Sulfathiazole Nasal Suspension; Topical	0.5% 5%	85 P-0205/CP	Tanya W Ross	New Dosage Form New Combination	Denied Nov 14, 1985
Pseudoephedrine Polisterex Capsule, Controlled Release; Oral	60mg	85 P-0334/CP	Pennwalt Pharm	New Salt New Ingredient	Denied Mar 19, 1986
Temazepam Soft Gelatin Capsule; Oral	10mg 20mg	85 P-0016/CP	Wyeth/AMHO	New Strength	Denied Sep 29, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Triamcinolone Acetonide Suspension; Injection	2.5mg/ml	85 P-0001/CP	GenDerm	New Strength	Denied Mar 4, 1985
Triamcinolone Acetonide Suspension; Injection	3mg/ml	84 P-0240/CP	Bay Pharmaceuticals	New Strength	Denied Mar 4, 1985

APPENDIX 5

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, THE FOLLOWING ABBREVIATIONS HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THIS PAGE FOR AN EXPLANATION OF THE EXCLUSIVITY ABBREVIATIONS FOUND IN THE ADDENDUM.

ABBREVIATIONS

NC	NEW COMBINATION
NCE	NEW CHEMICAL ENTITY
NDF	NEW DOSAGE FORM
NE	NEW ESTER OR SALT OF AN ACTIVE INGREDIENT
NP	NEW PRODUCT
NR	NEW ROUTE
PP	PARENTERAL IN PLASTIC CONTAINER
RTO	PRESCRIPTION TO OTC STATUS CHANGE
NS	NEW STRENGTH
D	NEW DOSING SCHEDULE (SEE REFERENCE, BELOW)
I	NEW INDICATION (SEE REFERENCE, BELOW)
ODE	ORPHAN DRUG EXCLUSIVITY

REFERENCES

NEW DOSING SCHEDULE

D-1	ONCE A DAY APPLICATION
D-2	ONCE DAILY DOSING
D-3	SEVEN DAYS/SEVEN DAYS/SEVEN DAYS DOSING SCHEDULE
D-4	SEVEN DAYS/FOURTEEN DAYS DOSING SCHEDULE
D-5	TEN DAYS/ELEVEN DAYS DOSING SCHEDULE

(continued)

APPENDIX 5

(continued)

NEW DOSING SCHEDULE

D-6	SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE
D-7	BID DOSING
D-8	INTRAVENOUS, EPIDURAL AND INTRATHECAL DOSING
D-9	NARCOTIC OVERDOSE IN ADULTS
D-10	NARCOTIC OVERDOSE IN CHILDREN
D-11	POSTOPERATIVE NARCOTIC DEPRESSION IN CHILDREN
D-12	BEDTIME DOSING OF 800MG FOR TREATMENT

NEW INDICATION

I-1	SEVERE HYPERTENSION IN PEDIATRICS AND NON-MALIGNANT HYPERTENSION
I-2	DYSMENORRHEA
I-3	TREATMENT OF TINEA VERSICOLOR
I-4	SYMPTOMATIC GASTROESOPHAGEAL REFLUX
I-5	NEPHROTOMOGRAPHY
I-6	CONTRAST ENHANCEMENT IN CRANIAL COMPUTED TOMOGRAPHY
I-7	VENOGRAPHY OF LOWER EXTREMITIES
I-8	WHOLE-BODY COMPUTED TOMOGRAPHY
I-9	GATED CARDIAC POOL IMAGING
I-10	POST-MYOCARDIAL INFARCTION
I-11	COLORECTAL SURGERY
I-12	NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY
I-13	CISPLATIN INDUCED EMESIS
I-14	DIABETIC GASTROPARESIS
I-15	SHORT TERM TREATMENT OF GASTRIC ULCER DISEASE
I-16	ACROMEGALY

(continued)

APPENDIX 5

(continued)

NEW INDICATION

	I-17	PITUITARY TUMORS
	I-18	POSTMENOPAUSAL OSTEOPOROSIS
	I-19	ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
	I-20	CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE
	I-21	ACUTE/OTITIS/MEDIA
	I-22	EXERCISE INDUCED BRONCHOSPASMS
	I-23	MYOCARDIAL INFARCTION OR STROKE
	I-24	COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL
	I-25	BLASTOMYCOSES DERMATITIDES
	I-26	PEDIATRIC SUBARACHNOID VASCULAR
	I-27	PETRIELLIDIUM BOYDII INFECTION
	I-28	HEREDITARY ANGIOEDEMA
	I-29	INTRACORONARY USE
	I-30	PEDIATRIC USE
	I-31	DIRECT ISOTOPIC CYSTOGRAPHY
	I-32	POSTPARTUM HEMORRHAGE
	I-33	USE IN METHODONE INDUCED RESPIRATORY DEPRESSION
	I-34	PROLACTIN SECRETING ADENOMAS
	I-35	ANGINA PECTORIS DUE TO CORONARY ATHEROSCLEROSIS
	I-36	ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
	I-37	SPINAL ANESTHESIA
	I-38	PATIENT PREOPERATIVE SKIN PREPARATION
> DLT >	I-39	ADJUVANT/WITH/CHEMOTHERAPY/FOR/TREATMENT/OF/BREAST/CANCER/FOLLOWING/MASTECTOMY
	I-40	ANTIDOTE FOR ACETAMINOPHEN OVERDOSE

(continued)

APPENDIX 5

(continued)

NEW INDICATION

	I-41	MANAGEMENT OF HYPOCALCEMIA AND RESULTANT METABOLIC BONE DISEASE IN RENAL DIALYSIS PATIENTS
	I-42	MAINTENANCE THERAPY AT REDUCED DOSE FOLLOWING HEALING OF ACUTE DUODENAL ULCER
	I-43	TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE
	I-44	TREATMENT OF SEVERE RECALCITRANT DERMATOPHYTE INFECTIONS
	I-45	ACCELERATE BARIUM TRANSIT THEREBY DECREASING TIME AND EXTENT OF RADIATION TO INTESTINAL TRACT
	I-46	TREATMENT OF SMALL CELL LUNG CANCER IN COMBINATION WITH OTHER APPROVED CHEMOTHERAPEUTIC DRUGS
	I-47	USE IN BALANCED ANESTHESIA
	I-48	MANAGEMENT OF FAMILIAL OR HEREDITARY ESSENTIAL TREMOR
>ADD>	I-49	ADJUNCT TO COUMARIN ANTICOAGULANTS IN PREVENTION OF POSTOPERATIVE THROMBOEMBOLIC COMPLICATIONS OF CARDIAC VALVE REPLACEMENTS
>ADD>	I-50	TREATMENT OF ARRHYTHMIAS
>ADD>	I-51	MANAGEMENT OF ESSENTIAL HYPERTENSION
>ADD>	I-52	CERVICAL MYELOGRAPHY
>ADD>	I-53	USE AS SINGLE AGENT TO DELAY BREAST CANCER RECURRENCE FOLLOWING TOTAL MASTECTOMY AND AXILLARY DISSECTION IN POSTMENOPAUSAL WOMEN

DRUG PRODUCTS APPROVED UNDER SECTION 505 OF THE ACT
BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES

NO SEPTEMBER 1985 - DECEMBER 1986 ACTIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	/12142/001/	/4537883/	/AUG/27,/2002/		
	/12142/002/	/4537883/	/AUG/27,/2002/		
	/12142/003/	/4537883/	/AUG/27,/2002/		
	/12142/004/	/4537883/	/AUG/27,/2002/		
	/12142/005/	/4537883/	/AUG/27,/2002/		
	12142 006	4537883	AUG 27, 2002		
	12142 007	4537883	AUG 27, 2002		
	12142 008	4537883	AUG 27, 2002		
	12142 009	4537883	AUG 27, 2002		
	12142 010	4537883	AUG 27, 2002		
	12365 005	4534973	AUG 13, 2002		
	12366 002	4534974	AUG 13, 2002		
>_ADD_>	12836 003			I-49	DEC 22, 1989
	13601 001			I-40	JAN 31, 1988
	13601 002			I-40	JAN 31, 1988
	14013 003	4619935	OCT 28, 2003		
	/14715/001/	/3428735/	/FEB/18,/1986/		
	14715 004	3428735	FEB 18, 1986		
	/16273/001/	/4324779/	/APR/13,/1999/		
	/16273/002/	/4324779/	/APR/13,/1999/		
	/16273/003/	/4324779/	/APR/13,/1999/		
	/16363/001/	/4324779/	/APR/13,/1999/		
	16418 001			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 002			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 003			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 004			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 009			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 010			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16636 002			D-9	SEP 24, 1986
				D-10	
				D-11	
				I-33	
	16983 001			I-36	SEP 09, 1988
	16990 001	3634582	JAN 11, 1989		
		3860618	JAN 14, 1992		

(continued)

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	17560 001	RE28636	JUN 02, 1987	I-21	SEP 24, 1986
	17560 002	RE28636	JUN 02, 1987	I-21	SEP 24, 1986
	17581 001	3998966	DEC 21, 1993	N$	SEP 24, 1986
	17601 001	3419565	DEC 31, 1985		
		3717647	FEB 20, 1990		
	17613 001	3839573	OCT 01, 1991		
	17619 001	3839573	OCT 01, 1991		
	17688 001	4324779	APR 13, 1999		
	17697 001			I-45	AUG 25, 1989
	17717 001	3839573	OCT 01, 1991		
	17760 001			NDF	SEP 04, 1988
	17768 001	3855140	DEC 17, 1991	I-38	SEP 24, 1986
		3960745	DEC 17, 1991		
	17785 001			NDF	MAR 07, 1989
	17862 001	4536386	AUG 20, 2002	I-12	SEP 24, 1986
				I-13	SEP 24, 1986
				I-14	SEP 24, 1986
	17862 002	4536386	AUG 20, 2002	I-12	SEP 24, 1986
				I-13	SEP 24, 1986
				I-14	SEP 24, 1986
	17862 003	4536386	AUG 20, 2002	I-12	SEP 24, 1986
				I-13	SEP 24, 1986
				I-14	SEP 24, 1986
	17920 005	3950333	APR 13, 1993	D-12	APR 30, 1989
		4024271	MAY 17, 1994		
DLT	17970 001	4536516	AUG 20, 2002	I-39	DEC 16, 1988
>ADD<	17970 001	4536516	AUG 20, 2002	I-53	DEC 03, 1989
	18024 001			I-47	OCT 23, 1989
	18024 002			I-47	OCT 23, 1989
	18044 001			I-41	JAN 22, 1989
	18044 002			I-41	JAN 22, 1989
	18052 001	3839573	OCT 01, 1991		
	18053 003			I-37	SEP 25, 1988
	18063 005	3935267	JAN 27, 1993		
		3982021	SEP 21, 1993		

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
18147 002	RE29668	DEC 10, 1991		
	4100347	JUL 11, 1995		
	3927002	DEC 16, 1992		
18147 003	RE29668	DEC 10, 1991		
	4100347	JUL 11, 1995		
	3927002	DEC 16, 1992		
18154 001	3461461	AUG 12, 1986		
	3461461	MAY 07, 1985		
18154 003	3461461	AUG 12, 1986		
	3461461	MAY 07, 1985		
18155 001			ODE	OCT 03, 1991
18181 001	3839573	OCT 01, 1991		
18182 001	3839573	OCT 01, 1991		
18183 001	3839573	OCT 01, 1991		
18217 001	4035376	JUL 12, 1994	NCE	DEC 24, 1990
18230 001	3839573	OCT 01, 1991		
18240 001			I-35	SEP 04, 1988
18240 002			I-35	SEP 04, 1988
18257 001	4237068	DEC 02, 1997		
	4237068	NOV 09, 1998		
18257 002	4237068	DEC 02, 1997		
	4237068	NOV 09, 1998		
18401 001	3433791	MAR 18, 1986		
18423 001	3855140	DEC 17, 1991		
	3960745	DEC 17, 1991		
18470 001	4347242	JUN 30, 1998	NCE	OCT 31, 1991
18471 001			NDF	MAY 30, 1989
18482 001	3784684	JAN 08, 1991		
18482 002	3644627	FEB 22, 1989		
	3784684	JAN 08, 1991		
18489 001	RE31463	APR 12, 1994	NCE	OCT 31, 1991
18506 001	3419565	DEC 31, 1985		
	3717647	FEB 20, 1990		

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	18509 001			NP	AUG 07, 1988
	18513 002			ODE	JUL 28, 1990
	18533 001			I-44	JUN 30, 1989
	18587 003	3658993	APR 25, 1989	NCE	SEP 07, 1992
>ADD>	18593 001			I-50	DEC 16, 1989
>ADD>				I-51	DEC 16, 1989
>ADD>	18593 002			I-50	DEC 16, 1989
>ADD>				I-51	DEC 16, 1989
>ADD>	18602 003	3562257	FEB 09, 1988	NCE	NOV 05, 1992
>ADD>	18602 004	3562257	FEB 09, 1988	NCE	NOV 05, 1992
>ADD>	18634 001			NR	DEC 17, 1989
	18644 001	3819706	JUN 25, 1991	NCE	DEC 30, 1990
		3885046	MAY 20, 1992		
		4057323	MAR 26, 2002		
		4347257	AUG 31, 1999		
		4393078	JUL 12, 2000		
		4425363	JAN 10, 2001		
		4435449	MAR 06, 2001		
		4438138	MAR 20, 2001		
	18644 002	3819706	JUN 25, 1991	NCE	DEC 30, 1990
		3885046	MAY 20, 1992		
		4057323	MAR 26, 2002		
		4347257	AUG 31, 1999		
		4393078	JUL 12, 2000		
		4425363	JAN 10, 2001		
		4435449	MAR 06, 2001		
		4438138	MAR 20, 2001		
	18644 003	3819706	JUN 25, 1991	NCE	DEC 30, 1990
		3885046	MAY 20, 1992		
		4057323	MAR 26, 2002		
		4347257	AUG 31, 1999		
		4393078	JUL 12, 2000		
		4425363	JAN 10, 2001		
		4435449	MAR 06, 2001		
		4438138	MAR 20, 2001		
	18654 001	4280957	JUL 28, 1998	NCE	DEC 20, 1990

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	18677 001	4087545	MAY 02, 1995	NCE	DEC 26, 1990
		4087547	MAY 02, 1995		
	/18682/001/	/4062966/	/DEC/13,/1993/	/NCE/	/SEP/24,/1986/
	18682 001	4062966	DEC 13, 1994	NCE	FEB 18, 1993
	18683 001	4393871	JUL 19, 2000		
	/18689/001/	/3708579/	/JAN/02,/1996/		
	18689 001	3708579	JAN 02, 1992		
	18701 001	3438991	APR 15, 1986	NE	JAN 14, 1989
	18703 001			I-42	MAY 30, 1989
	18703 001			I-43	MAY 30, 1989
	18703 002	4128658	DEC 05, 1995	NCE	JUN 09, 1993
		4521431	JUN 04, 2002	I-15	JUN 28, 1988
				I-42	MAY 30, 1989
				I-43	MAY 30, 1989
	18705 001			NDF	OCT 31, 1988
	18708 001	3845039	OCT 29, 1991	NCE	DEC 27, 1990
		3920818	NOV 18, 1992		
	18713 001	/3839573/	/OCT/01,/1991/		
	18731 001	3177634	FEB 20, 1990	NCE	SEP 29, 1991
		4182763	JAN 08, 1997		
	18731 002	3177634	FEB 20, 1990	NCE	SEP 29, 1991
		4182763	JAN 08, 1997		
	18735 001	4001323	JAN 04, 1994	NCE	DEC 31, 1990
	18735 002	4001323	JAN 04, 1994	NCE	DEC 31, 1990
	18735 003	4001323	JAN 04, 1994	NCE	DEC 31, 1990
	18735 004	4001323	JAN 04, 1994	NCE	DEC 31, 1990
	/18738/001/	/4055652/	/OCT/25,/1994/	/NCE/	/AUG/30,/1990/
	18738 001	4055652	OCT 25, 1996	NCE	AUG 30, 1990
	18754 002	3641127	FEB 08, 1989	NCE	JAN 09, 1991
	18754 003	3641127	FEB 08, 1989	NCE	JAN 09, 1991
	18768 001			I-46	SEP 04, 1989
	/18770/001/	/4138581/	/FEB/06,/1996/	/NCE/	/DEC/28,/1989/
	18770 001	4138581	FEB 06, 1998	NCE	DEC 28, 1989
	18813 001	/3839573/	/OCT/01,/1991/		
>ADD>	18817 001			I-50	DEC 16, 1989
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>ADD>	18817 002			I-50	DEC 16, 1989
>ADD>				I-51	DEC 16, 1989
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	18830 001	3900481	AUG 19, 1992	NCE	OCT 31, 1990
	18830 001	4005209	JAN 25, 1994	NCE	OCT 31, 1990
	18830 002	3900481	AUG 19, 1992	NCE	OCT 31, 1990
	18830 002	4005209	JAN 25, 1994	NCE	OCT 31, 1990

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
18859 001	4211771	JUL 08, 1997	NCE	DEC 31, 1990
	RE29835	MAR 19, 1991		
18873 002	3954872	MAY 04, 1993	NCE	DEC 30, 1990
	4031244	JUN 21, 1994		
18873 003	3954872	MAY 04, 1993	NCE	DEC 30, 1990
	4031244	JUN 21, 1994		
18873 004	3954872	MAY 04, 1993	NCE	DEC 30, 1990
	4031244	JUN 21, 1994		
18874 001	3697559	OCT 10, 1989	NDF	SEP 24, 1989
18874 001	4308264	DEC 29, 1998		
18874 002	3697559	OCT 10, 1989	NDF	SEP 24, 1989
18874 002	4308264	DEC 29, 1998		
18887 001	3686412	AUG 22, 1989	NDF	DEC 05, 1988
	3777033	AUG 22, 1989		
	3860618	JAN 14, 1992		
	4405598	SEP 20, 2000		
18891 001	4559222	DEC 17, 2002		
18891 002	4559222	DEC 17, 2002		
18891 003	4559222	DEC 17, 2002		
/18917/001/	/3857952/	/DEC/31,/1991/		
18917 001	3857952	DEC 31, 1993		
/18917/003/	/3857952/	/DEC/31,/1991/		
18917 003	3857952	DEC 31, 1993		
18928 001	4221778	SEP 09, 1997		
18932 001			ODE	NOV 20, 1991
18948 001			NCE	DEC 27, 1990
			ODE	DEC 27, 1992
/18949/001/	/3878217/	/APR/15,/1992/	/NCE	/MAY/08,/1990/
18949 001	3878217	APR 15, 1994	NCE	MAY 08, 1990
	/3866526/	/APR/23,/1991/		
	/3965257/	/JUN/22,/1993/		
	/3966949/	/JUN/29,/1993/		
	/4254129/	/MAR/03,/1998/		
	/4285957/	/AUG/25,/1998/		

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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		>ADD>		
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		>ADD>		
18956 001	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 19980	I-52	NOV 26, 1989
18956 002	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998	I-52	NOV 26, 1989
18956 003	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998		
18956 004	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998		
18972 001			NCE	DEC 24, 1990
18981 002	3931195	JAN 06, 1993	NCE	DEC 24, 1991
18981 003	3931195	JAN 06, 1993	NCE	DEC 24, 1991
18981 004	3931195	JAN 06, 1993	NCE	DEC 24, 1991
18985 001	4544554	JUL 23, 2002		
	4616006	OCT 07, 2003		
18985 002	4544554	JUL 23, 2002		
	4616006	OCT 07, 2003		
18998 001	4374829	FEB 22, 2000	NCE	DEC 24, 1990
18998 002	4374829	FEB 22, 2000	NCE	DEC 24, 1990
18998 003	4374829	FEB 22, 2000	NCE	DEC 24, 1990
19009 001			NCE	DEC 30, 1991
19011 001			NP	SEP 24, 1986
19028 001			NP	AUG 13, 1989
19032 001	3632645	JAN 04, 1989	NCE	OCT 27, 1991
/19044/001/	/4335059/	/JUN/15,/1999/	/NCE/	/DEC/23,/1990/
19044 001	4335095	JUN 15, 1999	NCE	DEC 23, 1990
19059 001	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
19059 002	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
19059 003	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
19069 001	/3839573/	/OCT/01,/1991/		
19071 001			ODE	AUG 30, 1992
			NP	AUG 30, 1988
19079 001			NE	FEB 11, 1989
19081 002	4379454	APR 12, 2000	NDF	SEP 10, 1989
	4144317	SEP 09, 1992		
	3948262	JUL 29, 1992		

(continued)

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	19081 003	4379454	APR 12, 2000	NDF	SEP 10, 1989
		4144317	SEP 09, 1992		
		3948262	JUL 29, 1992		
	19084 001	4335125	JUN 15, 1999	NDF	DEC 31, 1988
>_ADD_>	19085 001	3681500	AUG 01, 1989	NCE	DEC 29, 1991
	19090 001	4585790	APR 29, 2003		
	19107 001			NCE	OCT 17, 1990
	19107 001			ODE	OCT 17, 1992
>_ADD_>	19152 001			NDF	DEC 16, 1989
	19193 001			NCE	OCT 31, 1991
	19194 001			NCE	NOV 11, 1990
				ODE	NOV 11, 1992
	19215 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990
	19219 002	3641152	FEB 08, 1989	NCE	DEC 19, 1990
	19221 001	4374829	FEB 22, 2000	NC	OCT 31, 1989
		4472380	SEP 18, 2001		
	19257 001			NDF	APR 10, 1989
				ODE*	DEC 27, 1992
	19259 001	3980778	SEP 14, 1993		
	19260 001	3980778	SEP 14, 1993		
	19264 001			ODE	OCT 16, 1991
	19270 001	4252984	FEB 24, 1998	NCE	AUG 30, 1990
		4311708	JAN 19, 1999		
		4342783	AUG 03, 1999		
>_ADD_>	19280 001	3950405	APR 13, 1993	NCE	DEC 30, 1991
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>_ADD_>	19281 001	3950405	APR 13, 1993	NCE	DEC 30, 1991
>_ADD_>				ODE	DEC 30, 1993
	19322 001	3721687	MAR 20, 1990	NCE	DEC 27, 1990
	19323 001	3721687	MAR 20, 1990	NCE	DEC 27, 1990
>_ADD_>	19353 001			NCE	DEC 29, 1991
>_ADD_>	19355 001	4062966	DEC 13, 1994	NCE	FEB 18, 1993
	19359 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990
	19368 001	4205086	MAY 27, 1997	NCE	OCT 29, 1990
				ODE	OCT 29, 1992

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	19369 001	4215215	JUL 29, 1997	NCE	SEP 30, 1991
		4200647	APR 29, 1997		
	19369 002	4215215	JUL 29, 1997	NCE	SEP 30, 1991
		4200647	APR 29, 1997		
	19384 002	4146719	MAR 27, 1996	NCE	OCT 31, 1991
>_ADD_>	19386 002			NCE	DEC 31, 1991
>_ADD_>	19404 001			NCE	DEC 31, 1991
	19412 001			NS	MAR 10, 1989
	19412 002			NS	MAR 10, 1989
	19412 003			NS	MAR 10, 1989
	19412 004			NS	MAR 10, 1989
	19415 001			NE	SEP 18, 1989
	19425 001	4012444	MAR 15, 1994	NCE	AUG 01, 1994
		4066755	JAN 03, 1995		
	19434 001	3950333	APR 13, 1993		
		4024271	MAY 17, 1994		
	19435 001	4024163	MAY 17, 1994	NCE	MAR 31, 1991
	19439 001			NS	JUN 13, 1989
	19441 001			NC	JUL 11, 1989
	19462 001	4283408	AUG 11, 1998	NCE	OCT 15, 1991
	19462 002	4283408	AUG 11, 1998	NCE	OCT 15, 1991
	19463 001	3655663	APR 11, 1989	NP	NOV 05, 1989
	19463 001	4195085	MAR 25, 1997		
	19463 002	3655663	APR 11, 1989	NP	NOV 05, 1989
	19463 002	4195085	MAR 25, 1997		
	19478 001	3644627	FEB 22, 1989		
		3784684	JAN 08, 1991		
	19478 002	3644627	FEB 22, 1989		
		3784684	JAN 08, 1991		
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>_ADD_>				ODE	DEC 15, 1993
	19510 001	4283408	AUG 11, 1998	NCE	OCT 15, 1991
	19518 001			NS	AUG 06, 1989

*REFER TO APPENDIX I NARRATIVE

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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> ADD >	19557 002	3524844	AUG 18, 1987	NCE	NOV 10, 1993
> ADD >	19593 001	4128658	DEC 05, 1995	NCE	JUN 09, 1993
> ADD >		4521431	JUN 04, 2002		
> ADD >		4585790	APR 29, 2003		
> ADD >	19600 001	4454152	JUN 12, 2001	NDF	OCT 30, 1989

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