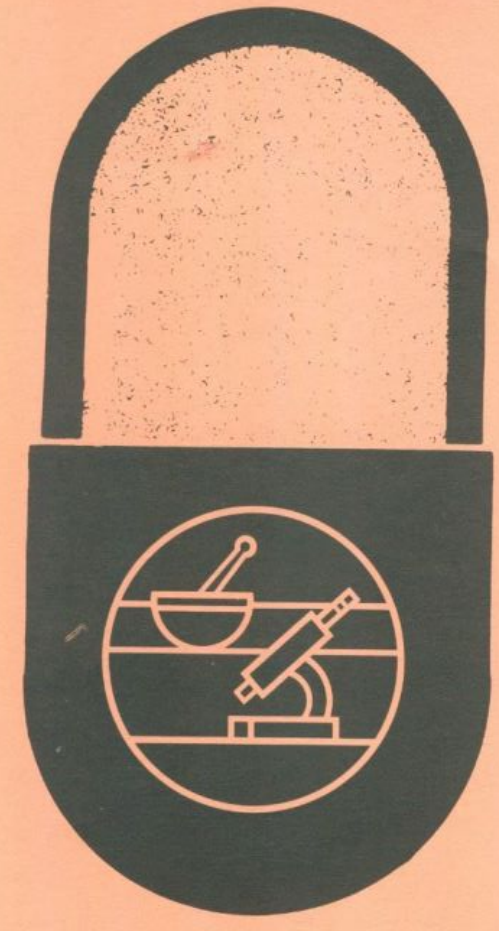
CUMULATIVE SUPPLEMENT 9 AUG'85-MAY'86



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

MAY 1986

CONTENTS

A. INTRODUCTION

1. How to Use the Cumulative Supplement
2. Applicant (Name) Changes
3. Prednisone Bioequivalence
4. OTC Drug Products
5. Products Requiring Revised Labeling for Full Approval
6. Injectable Product Package Size Designation
7. Report of Counts for the Prescription Drug Product List

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

6th EDITION

CUMULATIVE SUPPLEMENT

MAY 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

(continued)

APPLICANT (NAME) CHANGES

(continued)

Former Applicant (Name)	New Applicant (Name)	New Abbreviated Name
AM MCGAW/AM HOSP	KENDALL MCGAW LABORATORIES, INC	KENDALL MCGAW LABS
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	MK-K LABORATORIES

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

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
isosorbide dinitrate	AUG 3, 1984 (49 FR 31151)
nandrolone decanoate	JUL 15, 1983 (48 FR 32395)
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)
neomycin sulfate, polymyxin B sulfate, bacitracin zinc, and hydrocortisone [topical ointment]	MAY 4, 1984 (49 FR 19147)
nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
sulfanilamide and aminacrine	AUG 22, 1983 (48 FR 38097)
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)	OCT '85	JAN '86	APR '86
DRUG PRODUCTS LISTED	8048	8230	8515	8683
SINGLE SOURCE	2096 (26.0%)	2100 (25.5%)	2144 (25.1%)	2138 (24.6%)
MULTISOURCE(1)	5952 (74.0%)	6130 (74.5%)	6371 (74.9%)	6545 (75.4%)
THERAPEUTICALLY EQUIVALENT	4864 (60.5%)	5034 (61.2%)	5263 (61.8%)	5422 (62.5%)
NOT THERAPEUTICALLY EQUIVALENT	1054 (13.1%)	1058 (12.9%)	1070 (12.6%)	1068 (12.3%)
EXCEPTIONS(2)	34 (0.4%)	38 (0.4%)	38 (0.5%)	55 (0.6%)
NEW MOLECULAR ENTITIES APPROVED	-	5	21	1
NUMBER OF APPLICANTS	306	313	322	324

B. ACTIVITY FOR SUPPLEMENT NUMBER 9

	MAY '86	CUMULATIVE
DRUG PRODUCTS ADDED:	60	60
NEWLY APPROVED	57	57
DESI EFFECTIVE	0	0
REMARKETED	3	3
DRUG PRODUCTS REMOVED:	0	0
WITHDRAWN APPROVAL	0	0
RX TO OTC SWITCH	0	0
NET GAIN IN DRUG PRODUCTS	60	60
SINGLE SOURCE PRODUCTS APPROVED	5	5
MULTISOURCE DRUG PRODUCTS APPROVED	55	55
NEW MOLECULAR ENTITIES APPROVED:	0	0
AS THE ENTITY	0	0
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	0

(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

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
>ADD> AA REID-ROWELL 356.4MG;30MG;16MG¤ N88584 001
MAR 04, 1986

>ADD> SYNALGOS-DC-A
>ADD> 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 SUPERPHARM 300MG;30MG¤ N89184 001
OCT 18, 1985
>ADD> AA 300MG;30MG¤ N89253 001
>ADD> 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
>ADD> AA 300MG;60MG¤ N89254 001
>ADD> 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

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

TABLET; ORAL

	DURADYNE DHC			
AA	FOREST PHARM/FOREST	500MG;5MG		N87809 001
				MAR 17, 1983
> ADD >	**NORCET**			
> ADD > AA	HOLLOWAY PHARMS	500MG;5MG¤		N88871 001
> ADD >				MAY 15, 1986

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL

	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
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

ACYCLOVIR (PAGE 3-5)

CAPSULE; ORAL

	ZOVIRAX			
	BURROUGHS WELLCOME	200MG		N18828 001
				/JAN 24, 1985/
				JAN 25, 1985

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
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

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

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION

	AMINOSYN-PF 7%			
	ABBOTT LABORATORIES	7%¤		N19398 001
				SEP 06, 1985
	AMINOSYN II 3.5%			
	ABBOTT LABORATORIES	3.5%¤		N19438 001
				APR 03, 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

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

INJECTABLE; INJECTION

>DLT> /PERIPHRAMINE/
>ADD> 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; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC (PAGE 3-9)

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

AMINOCAPROIC ACID (PAGE 3-9)

INJECTABLE; INJECTION
AMINOCAPROIC ACID
AP QUAD PHARMS 250MG/ML¤ N70694 001 MAR 04, 1986

AMINOPHYLLINE (PAGE 3-10)

TABLET; ORAL
AMINOPHYLLINE
AB CORD LABORATORIES 100MG N85262 002
/BP/ /CORD LABORATORIES/ /100MG/ /N85262 002/

AMIODARONE HYDROCHLORIDE (PAGE 3-11)

TABLET; ORAL
CORDARONE
IVES LABS/AMHO 200MG¤ N18972 001 DEC 24, 1985

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

TABLET; ORAL
TRIAVIL 4-10
/BP/ /MS&D/MERCK/ /10MG;4MG/ /N14715 001/
BP MS&D/MERCK 10MG;4MG N14715 003

AMOXICILLIN (PAGE 3-15)

CAPSULE; ORAL
AMOXICILLIN
AB LABORATORIOS ATRAL 250MG¤ N62528 001 AUG 07, 1985
AB 500MG¤ N62528 002 AUG 07, 1985

UTIMOX
>DLT> AB /3/PARKE-DAVIS/W-L 250MG N62107 001
>DLT> AB /3/ 500MG N62107 002

POWDER FOR RECONSTITUTION; ORAL
>ADD> UTIMOX
>ADD> AB PARKE-DAVIS/W-L 125MG/5ML N62127 001
>ADD> AB 250MG/5ML N62127 002

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

> ADD > **BUTALBITAL W/ ASPIRIN AND CAFFEINE**

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

> ADD > **FIORINAL**

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

> ADD > **LANORINAL**

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

TABLET; ORAL

> ADD > **FIORINAL**

> ADD > AB SANDOZ PHARMS/SANDOZ 325MG;50MG;40MG¤ — N17534 003 APR 16, 1986

> ADD > **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; METHOCARBAMOL (PAGE 3-20)

TABLET; ORAL

METHOCARBAMOL AND ASPIRIN

AB MCNEIL CONSUMER PROD 325MG;400MG¤ — N89193 001 FEB 12, 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

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)

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
>ADD> AP ELKINS-SINN/AHROBINS 50MG/ML¤ N70545 001
>ADD> MAY 14, 1986
>ADD> AP 50MG/ML¤ N70546 001
>ADD> 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; DEXTROSE (PAGE 3-28)

INJECTABLE; INJECTION
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 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

BUPIVACAINE HYDROCHLORIDE (PAGE 3-29)

INJECTABLE; INJECTION
SENSORCAINE
>ADD> AP ASTRA PHARM PRODS 0.25%¤ N70552 001
>ADD> MAY 21, 1986
>ADD> AP 0.5%¤ N70553 001
>ADD> MAY 21, 1986
>ADD> AP 0.75%¤ N70554 001
>ADD> 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

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)

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

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

SOLUTION; INTRAPERITONEAL
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
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; 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

CARBACHOL (PAGE 3-36)

INJECTABLE; INJECTION

>ADD>		**CARBACHOL**			
>ADD>	AP	PHARMAFAIR	0.01%¤	N70292 001	MAY 21, 1986
>ADD>					
		MIOSTAT			
>ADD>	AP	ALCON LABORATORIES	0.01%	N16968 001	

CARBAMAZEPINE (PAGE 3-36)

TABLET; ORAL

>ADD>		**CARBAMAZEPINE**			
>ADD>	AB	COLMED LABORATORIES	200MG¤	N70300 001	MAY 15, 1986
>ADD>					
		TEGRETOL			
>ADD>	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			
		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

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

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
		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

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

CEFUROXIME SODIUM (PAGE 3-40)

INJECTABLE; INJECTION

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

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

CHLORAMPHENICOL (PAGE 3-42)

SOLUTION/DROPS; OPHTHALMIC

CHLORAMPHENICOL

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

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	HALSEY DRUG	100MG¤	N89321 001 JAN 16, 1986
AB		250MG¤	N88662 001 JAN 09, 1986

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL

CHLORTHALIDONE

AB	SIDMAK LABORATORIES	25MG¤	N88902 001 SEP 19, 1985
AB		50MG¤	N88903 001 SEP 19, 1985

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

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
> ADD > AB AM THERAPEUTICS 0.1MG N70881 001
> ADD > JUL 08, 1986 : MAY 27, 1986
> ADD > AB 0.2MG N70882 001
> ADD > JUL 08, 1986 : MAY 27, 1986
> ADD > AB 0.3MG N70883 001
> ADD > 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 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

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

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

CYCLOPHOSPHAMIDE (PAGE 3-57)

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

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-62)

INJECTABLE; INJECTION
DEXAMETHASONE SODIUM PHOSPHATE
AP CARTER-GLOGAU LABS EQ 4MG PHOSPHATE/ML N89169 001 APR 09, 1986

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)

TABLET; ORAL

	DEXCHLORPHENIRAMINE MALEATE			
AB	SIDMAK LABORATORIES	2MG¤	N88682 001	JAN 17, 1986
	POLARAMINE			
AB	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; 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

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

>ADD< 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

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

>ADD< 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

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

>ADD< 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 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; SODIUM CHLORIDE (PAGE 3-70)

INJECTABLE; INJECTION

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

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

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

DIAZEPAM

AB	CORD LABORATORIES	2MG¤	N70302 001	DEC 20, 1985
AB		5MG¤	N70303 001	DEC 20, 1985
AB		10MG¤	N70304 001	DEC 20, 1985
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
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	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
AB		5MG¤	N70361 001	SEP 04, 1985
AB		10MG¤	N70362 001	SEP 04, 1985

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)

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

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	

OINTMENT; TOPICAL

	DIFLORASONE DIACETATE			
BX	UPJOHN	0.05%¤	N19260 001	AUG 28, 1985
	FLORONE			
BX	UPJOHN	0.05%	N17994 001	

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

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
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

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

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	PARKE-DAVIS/W-L	EQ 50MG BASE¤	N62594 001	DEC 05, 1985
AB		EQ 100MG BASE¤	N62594 002	DEC 05, 1985

INJECTABLE; INJECTION

DOXYCYCLINE HYCLATE

AP	QUAD PHARMS	EQ 100MG BASE/VIAL¤	N62643 001	FEB 13, 1986
AP		EQ 200MG BASE/VIAL¤	N62643 002	FEB 13, 1986

DOXYCYCLINE HYCLATE (PAGE 3-79)

TABLET; ORAL

DOXYCYCLINE

AB	MEDICOPHARMA	EQ 100MG BASE¤	N62538 001	APR 07, 1986

DOXYCYCLINE HYCLATE

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

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

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

ERGOLOID MESYLATES (PAGE 3-82)

TABLET; ORAL
ERGOLOID MESYLATES

AB	BARR LABORATORIES	1MG	N88891 001	NOV 01, 1985

ERYTHROMYCIN (PAGE 3-83)

CAPSULE, ENTERIC-COATED PELLETS; ORAL
ERYC

	PARKE-DAVIS/W-L	250MG	N62618 001 SEP 25, 1985

ERYC 125

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

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; MEPROBAMATE (PAGE 3-87)

TABLET; ORAL
PMB 200

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

PMB 400

>DLT>	/BS/	/AYERST LABS/AMHO/	/0.4MG;400MG/	/N10971 003/
>ADD>	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

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 3-89)

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

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

ETHOXZOLAMIDE (PAGE 3-90)

TABLET; ORAL
ETHAMIDE

@	ALLERGAN PHARMS	125MG	N16144 001

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

>DLT>	/ERONALIDE/			
>DLT>	/SYNTEX LABS/SYNTEX/	/0.025MG/INH/	/N18340 001/	/AUG 17, 1984/
>DLT>				
>ADD>	AEROBID			
>ADD>	KEY PHARMACEUTICALS	0.025MG/INH	N18340 001	AUG 17, 1984
>ADD>				

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

FLUOROMETHOLONE (PAGE 3-93)

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	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

/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	SOLOPAK LABORATORIES	10MG/ML¤	N70023 001	FEB 05, 1986
AP		10MG/ML¤	N70078 001	FEB 05, 1986

FUROSEMIDE (PAGE 3-96)

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	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

GENTAMICIN SULFATE; SODIUM CHLORIDE (PAGE 3-98)

INJECTABLE; INJECTION
GENTAMICIN SULFATE IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	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

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

GUANABENZ ACETATE (PAGE 3-102)

TABLET; ORAL
WYTENSIN

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

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

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION

	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 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			
	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
> ADD >	**HEPARIN SODIUM PRESERVATIVE FREE**			
> ADD > AP	INVENEX/LYPHOMED	1,000 UNITS/ML¤	N17029 010	APR 28, 1986
> ADD >	**LIQUAEMIN SODIUM PRESERVATIVE FREE**			
> ADD > AP	ORGANON/AKZONA	1,000 UNITS/ML¤	N00552 011	APR 11, 1986
> ADD > AP		5,000 UNITS/ML¤	N00552 012	APR 11, 1986
> ADD > 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
> ADD > AA	MUTUAL PHARM	25MG¤	N89258 001 MAY 05, 1986
> ADD > 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
	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	25MG;250MG¤		N70688 001 APR 24, 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	CHELSEA LABORATORIES	25MG;40MG¤		N70301 001 APR 18, 1986
AB		25MG;80MG¤		N70305 001 APR 18, 1986
>ADD> AB	PUREPAC/KALIPHARMA	25MG;40MG¤		N70851 001 MAY 15, 1986
>ADD> 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/		/N10768 006/

HYDROCORTISONE (PAGE 3-112)

CREAM; TOPICAL

	HYDROCORTISONE			
AT	PHARMADERM/ALTANA	1%¤		N88845 001 FEB 27, 1986

LOTION; TOPICAL

	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

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

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	COLMED LABORATORIES	10MG¤	N89121 001	MAR 20, 1986	
AB		25MG¤	N89122 001	MAR 20, 1986	
AB		50MG¤	N89123 001	MAR 20, 1986	
>ADD> AB	MUTUAL PHARM	10MG¤	N89381 001	MAY 19, 1986	
>ADD> AB		25MG¤	N89382 001	MAY 19, 1986	
>ADD> 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	CHELSEA LABORATORIES	400MG¤	N70038 001	SEP 06, 1985
AB		600MG¤	N70041 001	SEP 06, 1985
AB	DANBURY PHARMACAL	400MG¤	N70436 001	AUG 21, 1985
AB		600MG¤	N70437 001	AUG 21, 1985
AB	MYLAN PHARMS	400MG¤	N70045 001	SEP 24, 1985
AB		600MG¤	N70057 001	SEP 24, 1985
AB	OHM LABORATORIES	400MG¤	N70818 001	DEC 26, 1985
>DLT> AB	/$/PAR PHARMACEUTICALS	300MG¤	N70328 001	AUG 06, 1985
AB		400MG¤	N70329 001	AUG 06, 1985
AB		600MG¤	N70330 001	AUG 06, 1985
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
	MOTRIN			
AB	@ UPJOHN	300MG	N17463 003	MAY 22, 1985
		800MG¤	N17463 005	

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	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	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
	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

ISONIAZID (PAGE 3-125)

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

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
> ADD > LACTULOSE
> ADD > AA ROXANE LABORATORIES 10GM/15ML N17906 001

LEUCOVORIN CALCIUM (PAGE 3-127)

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

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
AB	BARR LABORATORIES	0.5MG¤	N70472 001 DEC 10, 1985
AB		1MG¤	N70473 001 DEC 10, 1985
AB		2MG¤	N70474 001 DEC 10, 1985
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

∂	LEDERLE LABS/AM CYAN	EQ 10MG BASE	N17525 006
∂		EQ 25MG BASE	N17525 007
∂		EQ 50MG BASE	N17525 008

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

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

TABLET; ORAL

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

MEDROXYPROGESTERONE ACETATE (PAGE 3-136)

TABLET; ORAL

PROVERA

	UPJOHN	5MG	N11839 003

MENOTROPINS (PAGE 1-137)

INJECTABLE; INJECTION

PERGONAL

>DLT>	/SERONO LABS/	/150 IU/AMP/	/N17646 001/
>DLT>		/300 IU/AMP/	/N17646 002/
>ADD>	SERONO LABS	75 IU/AMP	N17646 001
>ADD>		150 IU/AMP	N17646 002 MAY 20, 1985

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 (PAGE 3-143)

INJECTABLE; INJECTION
METHOTREXATE SODIUM

> ADD >	AP	INTL PHARM PRODS	EQ 25MG BASE/ML¤	N88648 001	
> ADD >				MAY 09, 1986	
	AP	LYPHOMED	EQ 20MG BASE/VIAL¤	N88935 001	
				OCT 11, 1985	
	AP		EQ 50MG BASE/VIAL¤	N88936 001	
				OCT 11, 1985	
	AP		EQ 100MG BASE/VIAL¤	N89937 001	
				OCT 11, 1985	

MEXATE

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

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	BOLAR PHARMACEUTICAL	125MG¤	N70245 001	
			FEB 25, 1986	
AB		250MG¤	N70246 001	
			FEB 25, 1986	
AB		500MG¤	N70247 001	
			FEB 25, 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	
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	

METHYLDOPA (PAGE 3-144)

TABLET; ORAL
METHYLDOPA

AB	ROXANE LABORATORIES	125MG¤	N70192 001	
			APR 25, 1986	
AB		250MG¤	N70193 001	
			APR 25, 1986	
AB		500MG¤	N70194 001	
			APR 25, 1986	
AB	ZENITH LABORATORIES	250MG¤	N70098 001	
			FEB 20, 1986	
AB		500MG¤	N70343 001	
			FEB 20, 1986	

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-145)

INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE

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	
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	

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

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

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

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	DANBURY PHARMACAL	EQ 10MG BASE¤	N70511 001	JAN 22, 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	VITARINE	250MG	N18620 001	MAR 04, 1982
AB		500MG	N18620 002	JUN 02, 1983
	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

NABILONE (PAGE 3-150)

CAPSULE; ORAL

CESAMET			
ELI LILLY	1MG¤	N18677 001	DEC 26, 1985

NALBUPHINE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

	NALBUPHINE			
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 001	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, 1986 :	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 HCL

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
/3/		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

NANDROLONE DECANOATE

AO	LEMMON	50MG/ML¤	N88554 001 FEB 10, 1986
AO		50MG/ML	N87598 001 OCT 06, 1983

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

SOLUTION; IRRIGATION

NEOSPORIN G.U. IRRIGANT

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

NEOMYCIN AND POLYMYXIN B SULFATES

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

> ADD > NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE (3-153)

> ADD > OINTMENT; TOPICAL

> ADD > **NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE**

> ADD > AT	E FOUGERA/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62608 001 MAY 23, 1986

> ADD > **NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE**

> ADD > AT	PHARMADERM/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62607 001 MAY 23, 1986

> ADD > **MYTREX A**

> ADD > AT	SAVAGE LABS/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62609 001 MAY 23, 1986

NIFEDIPINE (PAGE 3-154)

CAPSULE; ORAL

ADALAT

AB	MILES PHARM/MILES	10MG¤	N19478 001 NOV 27, 1985

PROCARDIA

AB	PFIZER LABS/PFIZER	10MG	N18482 001

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

~~NOMIFENSINE MALEATE (PAGE 3-155)~~

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

NYSTATIN (PAGE 3-156)

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
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

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 AND TRIAMCINOLONE ACETONIDE
AT CLAY-PARK LABS 100,000 UNITS/GM;0.1%¤ N62280 002 OCT 10, 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

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		
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

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

	KALINORM		
BC	A/S BENZON	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

POTASSIUM CHLORIDE (PAGE 3-171)

TABLET, CONTROLLED RELEASE; ORAL

	SLOW-K			
BC	CIBA-GEIGY	8MEQ	N17476 002	

POTASSIUM CITRATE (PAGE 3-173)

TABLET; ORAL

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

PRALIDOXIME CHLORIDE (PAGE 3-174)

INJECTABLE; INJECTION

	PRALIDOXIME CHLORIDE			
AP	SURVIVAL TECHNOLOGY	300MG/ML	N18986 001 APR 26, 1983	
/AP/	/PROTOPAM/ /SURVIVAL TECHNOLOGY/	/300MG/ML/	/N18986 001/ /APR 26, 1983/	

PREDNISOLONE (PAGE 3-174)

SYRUP; ORAL

	PRELONE			
	MURO PHARMACEUTICAL	15MG/5ML¤	N89081 001 FEB 04, 1986	

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-175)

SUSPENSION/DROPS; OPHTHALMIC

	BLEPHAMIDE			
AT	ALLERGAN PHARMS	0.2%;10%	N12813 002	
	PREDSULFAIR II			
AT	PHARMAFAIR	0.2%;10%¤	N88837 001 DEC 24, 1985	

PREDNISOLONE SODIUM PHOSPHATE (PAGE 3-176)

SOLUTION; ORAL

>ADD>	PEDIAPRED			
>ADD>	FISONS	EQ 5MG BASE/5ML¤	N19157 001 MAY 28, 1986	

PREDNISONE (PAGE 3-176)

TABLET; ORAL

	DELTASONE				
AB	UPJOHN	5MG		N09986 002	
AB		10MG		N09986 006	
AB		20MG		N09986 007	
	PREDNISONE				
>DLT> /BX/	/DANBURY PHARMACAL/	/10MG/		/N85162 001/	
>ADD> AB	DANBURY PHARMACAL	10MG		N85162 001	
/BX/	/DURAMED PHARMS/	/20MG/		/N88396 001/	
AB	DURAMED PHARMS	20MG		N88396 001 OCT 04, 1983	
AB	MUTUAL PHARM	5MG¤		N89245 001 DEC 04, 1985	
AB		10MG¤		N89246 001 DEC 04, 1985	
AB		20MG¤		N89247 001 DEC 04, 1985	
/BX/	/WEST-WARD/	/50MG/		/N88465 001/	
AB	WEST-WARD	50MG		N88465 001 JUN 01, 1984	
AB	WEST-WARD	10MG¤		N88832 001 DEC 04, 1985	

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

INJECTABLE; INJECTION

	PROCAINAMIDE HCL			
AP	ABBOTT LABORATORIES	100MG/ML¤		N89069 001 FEB 12, 1986
AP		500MG/ML¤		N89070 001 FEB 12, 1986
AP	ELKINS-SINN/AHROBINS	100MG/ML¤		N89029 001 APR 17, 1986
AP		500MG/ML¤		N89030 001 APR 17, 1986
AP	PHARMAFAIR	100MG/ML¤		N88824 001 NOV 20, 1985
AP		500MG/ML¤		N88830 001 NOV 20, 1985
>ADD> AP	QUAD PHARMS	100MG/ML¤		N89256 001 MAY 30, 1986
>ADD> AP		500MG/ML¤		N89257 001 MAY 30, 1986

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

TABLET, CONTROLLED RELEASE; ORAL

	PROCAINAMIDE HCL			
AB	DANBURY PHARMACAL	250MG¤	N89026 001	OCT 22, 1985
AB		500MG¤	N89027 001	OCT 22, 1985
AB		750MG¤	N89042 001	OCT 22, 1985
	RHYTHMIN			
AB	SIDMAK LABORATORIES	250MG¤	N88958 001	DEC 02, 1985
AB		500MG¤	N88959 001	DEC 02, 1985

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

SYRUP; ORAL

	PROMETHAZINE			
AA	LIFE LABORATORIES	6.25MG/5ML¤	N89013 001	SEP 20, 1985

TABLET; ORAL

	PROMETHAZINE HCL			
BP	LEMMON	25MG¤	N89109 001	SEP 10, 1985

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

INJECTABLE; INJECTION

	INDERAL			
AP	AYERST LABS/AMHO	1MG/ML	N16419 001	
	PROPRANOLOL HCL			
AP	SOLOPAK LABORATORIES	1MG/ML¤	N70135 001	APR 15, 1986
AP		1MG/ML¤	N70136 001	APR 15, 1986
AP		1MG/ML¤	N70137 001	APR 15, 1986

TABLET; ORAL

	PROPRANOLOL			
AB	MYLAN PHARMS	10MG¤	N70211 001	NOV 19, 1985
AB		20MG¤	N70212 001	NOV 19, 1985
AB		40MG¤	N70213 001	NOV 19, 1985
AB		80MG¤	N70214 001	NOV 19, 1985

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL

	PROPRANOLOL HCL			
AB	BARR LABORATORIES	10MG¤	N70319 001	OCT 22, 1985
AB		20MG¤	N70320 001	OCT 22, 1985
AB		40MG¤	N70103 001	OCT 22, 1985
>ADD> AB	DANBURY PHARMACAL	10MG¤	N70175 001	MAY 13, 1986
>ADD> AB		20MG¤	N70176 001	MAY 13, 1986
>ADD> AB		40MG¤	N70177 001	MAY 13, 1986
>ADD> AB		80MG¤	N70178 001	MAY 13, 1986
AB	DURAMED PHARMS	10MG¤	N70306 001	SEP 09, 1985
AB		20MG¤	N70307 001	SEP 09, 1985
AB		40MG¤	N70308 001	SEP 09, 1985
AB		80MG¤	N70310 001	SEP 09, 1985
AB	MARTEC PHARMS	10MG¤	N70120 001	AUG 06, 1985
AB		20MG¤	N70121 001	AUG 06, 1985
AB		40MG¤	N70122 001	AUG 06, 1985
AB		80MG¤	N70124 001	AUG 06, 1985
AB	PAR PHARMACEUTICAL	80MG¤	N70221 001	APR 14, 1986
AB	WATSON LABS	20MG¤	N70549 001	APR 11, 1986
AB		40MG¤	N70550 001	APR 11, 1986

PROTAMINE SULFATE (PAGE 3-184)

INJECTABLE; INJECTION

	PROTAMINE SULFATE			
>ADD> AP	ELI LILLY	10MG/ML	N06460 002	
>ADD> AP	QUAD PHARMS	10MG/ML¤	N89306 001	MAY 30, 1986
>ADD>		50MG/VIAL¤	N89307 001	MAY 30, 1986
>ADD> AP	UPJOHN	50MG/VIAL	N07413 001	

SULCONAZOLE NITRATE (PAGE 3-197)

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

SUSPENSION; ORAL
> ADD > SEPTRA GRAPE
> ADD > AB BURROUGHS WELLCOME 200MG/5ML;40MG/5ML N17598 002
> ADD > FEB 12, 1986
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB PLANTEX/IKAPHARM 200MG/5ML;40MG/5ML N70028 001
JUN 02, 1987 : OCT 29, 1985

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB PHARM BASICS 400MG;80MG N70203 001
JUN 02, 1987 : NOV 08, 1985
AB 800MG;160MG N70204 001
JUN 02, 1987 : NOV 08, 1985
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
VAGITROL
LEMMON 15% N88718 001
SEP 19, 1985

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)

OPHTHALMIC; SOLUTION
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, SULFUR COLLOID KIT (PAGE 3-203)

INJECTABLE; INJECTION
> DLT > /SULFUR COLLOID KIT/
> DLT > /AP/ /SYNCOR INTL/ /N/A/ /N17858 001/
> ADD > AN-SULFUR COLLOID
> ADD > 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

QUAZEPAM (PAGE 3-186)

TABLET; ORAL
DORMALIN
SCHERING 15MG¤ N18708 001 DEC 27, 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 150
GLAXO EQ 150MG BASE N18703 001 JUN 09, 1983

ZANTAC 300
GLAXO EQ 300MG BASE¤ N18703 002 DEC 09, 1985

RIBAVIRIN (PAGE 3-189)

POWDER FOR RECONSTITUTION; INHALATION
VIRAZOLE
VIRATEK 6GM/VIAL¤ N18859 001 DEC 31, 1985

SECRETIN (PAGE 3-190)

INJECTABLE; INJECTION
SECRETIN-KABI
/KABIVITRUM/ /75CU/VIAL/ /N18290 001/
PHARMACIA/PHARMACIA 75CU/VIAL N18290 001

SILVER SULFADIAZINE (PAGE 3-191)

CREAM; TOPICAL
SILVADENE
/AT/ /MARION LABORATORIES/ /1%/ /N17381 001/
AB MARION LABORATORIES 1% N17381 001

SSD
/AT/ /TRAVENOL LABS/ /1%/ /N18578 001/ /FEB 25, 1982/

SILVER SULFADIAZINE (PAGE 3-191)

CREAM; TOPICAL
SSD
AB TRAVENOL LABS 1% N18578 001 FEB 25, 1982

ULTRA DERM
AB CHESEBROUGH-PONDS 1%¤ N18810 001 DEC 23, 1985

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

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

SULCONAZOLE NITRATE (PAGE 3-197)

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

SUSPENSION; ORAL
> ADD > SEPTRA GRAPE
> ADD > AB BURROUGHS WELLCOME 200MG/5ML;40MG/5ML¤ N17598 002
> ADD > FEB 12, 1986
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB PLANTEX/IKAPHARM 200MG/5ML;40MG/5ML¤ N70028 001
JUN 02, 1987 : OCT 29, 1985

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB PHARM BASICS 400MG;80MG¤ N70203 001
JUN 02, 1987 : NOV 08, 1985
AB 800MG;160MG¤ N70204 001
JUN 02, 1987 : NOV 08, 1985
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
VAGITROL
LEMMON 15%¤ N88718 001
SEP 19, 1985

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)

OPHTHALMIC; SOLUTION
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, SULFUR COLLOID KIT (PAGE 3-203)

INJECTABLE; INJECTION
> DLT > /SULFUR COLLOID KIT/
> DLT >/AP/ /SYNCOR INTL/ /N/A/ /N17858 001/
> ADD > AN-SULFUR COLLOID
> ADD > 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	
	/SOMAZ/			
	TEMAZ			
AB	QUANTUM PHARMICS	15MG¤	N70564 001	OCT 15, 1985
AB		30MG¤	N70547 001	OCT 15, 1985

THEOPHYLLINE (PAGE 3-206)

	CAPSULE, CONTROLLED RELEASE; ORAL			
	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
	ELIXIR; ORAL			
	THEOPHYL 225			
	/KNOLL PHARMACEUTICAL/	/112.5MG/15ML/	/N86485 001/	
	MCNEIL PHARM	112.5MG/15ML	N86485 001	
	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

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

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
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	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

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¤	SEP 24, 1986 :	N70495 001 MAR 14, 1986

TROPICAMIDE (PAGE 3-219)

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE

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

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

VANCOMYCIN HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION
VANCOCIN HCL
ELI LILLY EQ 1GM BASE/VIAL¤ N62476 002 MAR 21, 1986
EQ 1GM BASE/VIAL¤ N60180 002 MAR 21, 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
>ADD> AP	LYPHOMED	2.5MG/ML¤		N70348 001 MAY 01, 1986
>ADD> AP	QUAD PHARMS	2.5MG/ML¤		N70672 001 MAR 07, 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

VINCRISTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION
ONOCOVIN
AP ELI LILLY 1MG/ML N14103 003 MAR 07, 1984

VINCRISTINE SULFATE
AP QUAD PHARMS 1MG/ML¤ N70777 001 APR 29, 1986
>ADD> 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

CHLORHEXIDINE GLUCONATE (PAGE 3-224)

SOLUTION; TOPICAL
EXIDINE
XTTRIUM LABS 2%¤ N19422 001 DEC 17, 1985 >ADD<
2.5%¤ N19421 001 DEC 17, 1985 >ADD<

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
DIPHEN
BAY LABORATORIES 12.5MG/5ML¤ N70118 001 OCT 01, 1985
HYDRAMINE
NATL PHARM MFG/BARRE 12.5MG/5ML¤ N70205 001 JAN 28, 1986 >ADD<

DOXYLAMINE SUCCINATE (PAGE 3-225)

CAPSULE; ORAL
UNISOM
PFIZER LABS/PFIZER 25MG¤ N19440 001 FEB 05, 1986

IBUPROFEN (PAGE 3-225)

TABLET; ORAL
IBUPROFEN
BARR LABORATORIES 200MG¤ N70493 001 SEP 24, 1986 : DEC 24, 1985
CHELSEA LABORATORIES 200MG¤ N70605 001 SEP 24, 1986 : MAY 07, 1986
DANBURY PHARMACAL 200MG¤ N70435 001 SEP 24, 1986 : MAR 05, 1986
PAR PHARMACEUTICAL 200MG¤ N70481 001 SEP 24, 1986 : OCT 18, 1985
MEDIPREN
MCNEIL CONSUMER PROD 200MG¤ N70475 001 SEP 24, 1986 : FEB 06, 1986

INSULIN SUSPENSION, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION
HUMULIN BR
ELI LILLY 100UNITS/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, 1985

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

INJECTABLE; INJECTION
INSULATARD NPH HUMAN
NORDISK USA 100 UNITS/ML¤ N19449 001 MAY 30, 1986 >ADD<

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 100UNITS/ML¤ N19450 001 MAY 30, 1986 >ADD<

>ADD< OXYMETAZOLINE HYDROCHLORIDE (PAGE 3-228)

>ADD< SOLUTION/DROPS; OPHTHALMIC
>ADD< OCUCLEAR
>ADD< SCHERING 0.025% N18471 001
>ADD< 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

NO SEPTEMBER - MAY 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. 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.

Orphan Drug exclusive approval status (coded ODE) applies only to the 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 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	
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

(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
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
Trientine Hydrochloride 250mg	Cuprid Capsule; Oral	Merck Sharp and Dohme Res Labs	19194 001 Nov 8, 1985	ODE Nov 08, 1992

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
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	
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	
Diazepam (revised)	Jul 08, 1985	
Dicyclomine Hydrochloride	Aug 10, 1984	
Dipyridamole	Jul 05, 1983	
Disopyramide Phosphate	Jul 09, 1985	

(continued)

*New Addition

APPENDIX 3

(continued)

Name of Drug	Date	Revised Date
Dissolution Testing (General)	Apr 19, 1985	
Doxepin Hydrochloride	Apr 02, 1985	
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	
Methyltestosterone	Nov 16, 1979	
Metoclopramide	Dec 27, 1984	
Minoxidil	Apr 02, 1986	
Nitrofurantoin (Macrocrystalline)	Oct 29, 1985	
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	
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
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	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Elixir; Oral	160mg/5ml 6mg/5ml	86 P-0133/CP	New Strength	Approved May 21, 1986
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	300mg 30mg	85 P-0543/CP	New Dosage Form	Approved Mar 18, 1986
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	500mg 7.5mg	85 P-0543/ CP0002	New Dosage Form New Strength	Approved Mar 19, 1986
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	500mg 15mg	85 P-0543/ CP0002	New Dosage Form New Strength	Approved Mar 19, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 15mg	86 P-0161/CP	New Strength	Approved May 8, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 30mg	86 P-0161/CP	New Strength	Approved May 8, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 60mg	86 P-0161/CP	New Strength	Approved May 8, 1986
Acetaminophen; Hydrocodone Bitartrate Solution; Oral	500mg/15ml 5mg/15ml	84 P-0391/CP	New Dosage Form	Approved Jul 2, 1985
Acetaminophen; Oxycodone Hydrochloride Solution; Oral	325mg/5ml 5mg/5ml	85 P-0085/CP	New Dosage Form	Approved Aug 23, 1985
Acetaminophen; Oxycodone Hydrochloride Soft Gelatin Capsule; Oral	500mg 5mg	85 P-0543/ CP0003	New Dosage Form	Approved Mar 18, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Acetaminophen; Propoxyphene Hydrochloride Soft Gelatin Capsule; Oral	500mg 32mg	85 P-0581/CP	New Dosage Form New Strength	Approved Mar 18, 1986
Acetaminophen Suppository; Rectal	80mg	85 P-0403/CP	New Dosage Form (Pediatric)	Approved Oct 16, 1985
Aminocaproic Acid Injectable; Injection	500mg/ml 10ml/vial	85 P-0308/CP	New Strength	Approved Feb 12, 1986
Aminophylline Injectable; Injection	10mg/ml 10ml/vial	85 P-0459/CP	New Strength	Approved Feb 12, 1986
Aminophylline Injectable; Injection	50mg/ml 20ml/vial	85 P-0459/CP	New Strength	Approved Feb 12, 1986
Azatadine Maleate; Phenylpropanolamine Hydrochloride Sustained Release Capsule; Oral	1mg 75mg	85 P-0492/CP	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	Reason for Petition	Status
Benztropine Mesylate Syrup; Oral	0.5mg/5ml	85 P-0423/CP	New Dosage Form	Approved Oct 16, 1985
Bretylium Tosylate Injectable; Injection	100mg/ml	86 P-0157/CP	New Strength	Approved May 8, 1986
Brompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	12mg 120mg	85 P-0095/CP	New Combination New Dosage Form	Approved Dec 13, 1985
Chlorpheniramine Maleate; Phenylpropanolamine Hydrochloride Controlled-release Capsule; Oral	10mg 75mg	85 P-0149/CP	New Strength	Approved Dec 13, 1985
Chlorhexidine Gluconate Solution; Topical	1.5%	84 P-0417/CP	New Strength	Approved Sep 18, 1985
Codeine Phosphate; Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Syrup; Oral	10mg/5ml 1mg/5ml 12.5mg/5ml	85 P-0269/CP	New Combination	Approved Dec 6, 1985

(continued)

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Time Release Capsule; Oral	6mg 75mg	85 P-0238/ CP0002	New Combination	Approved Dec 13, 1985
Dexbrompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/CP	New Combination New Dosage Form	Approved Dec 13, 1985
Dexbrompheniramine Maleate; Pseudoephedrine Sulfate Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/ CP0002	New Dosage Form	Approved Jan 22, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Diazepam Solution; Oral	5mg/5ml	85 P-0090/CP	New Dosage Form	Approved Sep 19, 1985
Diazepam Syrup; Oral	2mg/5ml	85 P-0499/CP	New Dosage Form	Approved Feb 28, 1986
Diazepam Intensol Solution (Concentrate); Oral	5mg/ml	85 P-0566/CP	New Dosage Form	Approved Mar 18, 1986
Diphenhydramine Hydrochloride Concentrate; Oral	50mg/ml	84 P-0174/CP	New Strength	Approved Sep 11, 1985
Disulfiram Suspension; Oral	500mg/30ml	85 P-0215/CP	New Dosage Form	Approved Oct 8, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Estradiol Tablet; Oral	0.5mg	84 P-0308/CP	New Strength	Approved Mar 24, 1986
Fluorouracil Injectable; Injection	25mg/ml	85 P-0208/CP	New Strength	Approved Oct 8, 1985
Fluorouracil Injectable; Injection	50mg/20ml	86 P-0080/CP	New Strength	Approved Apr 2, 1986
Flurazepam Concentrate; Oral	30mg/ml	85 P-0081/CP	New Dosage Form	Approved Jul 10, 1985
Flurazepam Hydrochloride Solution; Oral	15mg/5ml	85 P-0091/CP	New Dosage Form	Approved Oct 25, 1985
Furosemide Solution; Oral	40mg/5ml	85 P-0106/ CP0002	New Strength	Approved Sep 19, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Furosemide Concentrate; Oral	80mg/ml	85 P-0106/CP	New Strength	Approved Sep 19, 1985
Haloperidol Solution; Oral	2mg/5ml	85 P-0076/ CP0002	New Strength	Approved Mar 26, 1986
Haloperidol Solution; Oral	5mg/5ml	85 P-0080/CP	New Strength	Approved Sep 19, 1985
Hydralazine Hydrochloride Solution; Oral	25mg/5ml	85 P-0074/CP	New Dosage Form	Approved Jul 3, 1985
Ibuprofen Capsule; Oral	200mg	84 P-0383/CP	New Dosage Form	Approved Jun 25, 1985
Ibuprofen Soft Gelatin Capsule; Oral	300mg 400mg 600mg	85 P-0563/CP	New Dosage Form	Approved Mar 19, 1986
Indomethacin Suspension; Oral	25mg/5ml	85 P-0077/ CP0002	New Dosage Form	Approved Jul 19, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Isoniazid Concentrate; Oral	50mg/ml	85 P-0468/CP	New Strength	Approved Dec 13, 1985
Ketoconazole Suspension; Oral	20mg/ml	85 P-0147/CP	New Dosage Form	Approved Sep 27, 1985
Leucovorin Calcium Tablet; Oral	15mg	85 P-0487/CP	New Strength	Approved Jan 28, 1986
Meperidine Hydrochloride Concentrate; Oral	100mg/ml	84 P-0175/CP	New Strength	Approved Jun 7, 1985
Metaproterenol Sulfate Solution; Inhalation	10mg/2.5ml	85 P-0509/CP	New Strength	Approved Feb 28, 1986
Metaproterenol Sulfate Solution; Inhalation	10mg/3ml	85 P-0429/ CP0002	New Strength	Approved Feb 28, 1986
Metaproterenol Sulfate Solution; Inhalation	15mg/3ml	85 P-0429/CP	New Strength	Approved Feb 28, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 20ml/vial	86 P-0036/CP	New Strength	Approved Mar 18, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 50ml/vial	85 P-0545/CP	New Strength	Approved Feb 28, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 50ml/vial	85 P-0540/CP	New Strength	Approved Feb 28, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 100ml/vial	85 P-0540/CP	New Strength	Approved Feb 28, 1986
Methyldopate Hydrochloride Injectable; Injection	50mg/ml 10ml/vial	85 P-0404/CP	New Strength	Approved Oct 25, 1985
Methyltestosterone Capsule; Oral	25mg	85 P-0067/CP	New Dosage Form	Approved Aug 23, 1985
Miconazole Nitrate Cream; Vaginal	4%	84 P-0398/CP	New Strength	Approved Mar 31, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Naloxone Hydrochloride Injectable; Injection	1mg/ml 5ml/vial	86 P-0079/CP	New Strength	Approved May 7, 1986
Naloxone Hydrochloride Injectable; Injection	1mg/ml 10ml/vial	86 P-0079/CP	New Strength	Approved May 7, 1986
Nitroglycerin Injectable; Injection	5mg/ml	86 P-0025/CP	New Strength	Approved Apr 1, 1986
Nitroglycerin Injectable; Injection	10mg/ml	85 P-0134/CP	New Strength	Approved Sep 19, 1985
Nitroglycerin in 5% Dextrose Injectable; Injection	10mg/100ml (500ml Container)	86 P-0099/CP	New Strength	Approved Apr 1, 1986
Nitroglycerin in 5% Dextrose Injectable; Injection	20mg/100ml (250ml Container)	86 P-0099/ CP0002	New Strength	Approved Apr 1, 1986
Nitroglycerin in 5% Dextrose Injectable; Injection	40mg/100ml (250ml and 500ml Containers)	86 P-0099/ CP0003	New Strength	Approved Apr 1, 1986
Probucol Tablet; Oral	500mg	85 P-0337/CP	New Strength	Approved Oct 25, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Procainamide Hydrochloride Tablet; Oral	375mg	85 P-0125/CP	New Strength	Approved Sep 19, 1985
Propranolol Hydrochloride Capsule; Oral	10mg 20mg 40mg 60mg 80mg 90mg	86 P-0045/CP	New Dosage Form	Approved Mar 19, 1986
Propranolol Hydrochloride Solution; Oral	40mg/5ml	85 P-0073/CP	New Dosage Form	Approved Jul 8, 1985
Propranolol Hydrochloride Concentrate; Oral	80mg/ml	85 P-0073/ CP0002	New Dosage Form	Approved Jul 19, 1985
Propranolol Hydrochloride Solution; Oral	20mg/5ml	85 P-0073/ CP0003	New Dosage Form	Approved Sep 24, 1985
Propranolol Hydrochloride Tablet, Constant-Release; Oral	160mg	85 P-0129/CP	New Dosage Form	Approved Sep 25, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Propranolol Hydrochloride Tablet, Controlled Release; Oral	80mg 120mg 160mg	85 P-0197/CP	New Dosage Form	Approved Sep 27, 1985
Pyridostigmine Bromide Tablet; Oral	30mg	85 P-0412/CP	New Strength	Approved Jan 22, 1986
Ritodrine Hydrochloride in Dextrose 5% Injectable; Injection	30mg/100ml 500ml Container	86 P-0100/CP	New Strength	Approved May 7, 1986
Scopolamine Transdermal System/24 Hour Film, Controlled Release; Percutaneous	1mg	85 P-0168/CP	New Strength (Dosing Interval)	Approved Sep 27, 1985
Spironolactone Syrup; Oral	25mg/5ml	85 P-0510/CP	New Dosage Form	Approved Jan 22, 1986
Spironolactone Oral; Injection	25mg/5ml	86 P-0055/CP	New Dosage Form	Approved Mar 28, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Theophylline Capsule; Oral	150mg 300mg	85 P-0175/CP	New Strength	Approved Oct 8, 1985
Vinblastine Sulfate Injectable; Injection	1mg/ml	86 P-0056/CP	New Dosage Form	Approved Mar 28, 1986
Vincristine Sulfate Injectable; Injection	2mg/vial	85 P-0016/CP	New Dosage Form	Approved Nov 8, 1985

APPENDIX 4

II. Petitions Denied

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	650mg 10mg	85 P-0015/CP	New Strength	Denied Nov 7, 1985
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	750mg 7.5mg	85 P-0169/CP	New Strength	Denied Nov 7, 1985
Aminocaproic Acid Injectable; Injection	500mg/ml	85 P-0064/CP	New Strength	Denied May 29, 1985
Aminophylline Injectable; Injection	10mg/ml	85 P-0066/CP	New Strength	Denied May 3, 1985
Aminophylline Injectable; Injection	50mg/ml	85 P-0066/CP	New Strength	Denied May 3, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Cholecalciferol Capsule; Oral Capsule; Oral	1.25mg	84 P-0161/CP	New Active Ingredient	Denied Feb 13, 1986
Codeine Phosphate; Ibuprofen Capsule; Oral	30mg 200mg	84 P-0388/CP	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Capsule; Oral	60mg 200mg	84 P-0388/CP	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Tablet; Oral	30mg 200mg	84 P-0388/CP	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Tablet; Oral	60mg 200mg	84 P-0388/CP	New Combination	Denied Sep 16, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Diatrizoate Meglumine; Lidocaine Hydrochloride Injectable; Injection	60% 1.5mg/ml	84 P-0325/CP	New Combination	Denied Sep 3, 1985
Diazepam Intensol Concentrate; Oral	10mg/ml	85 P-0075/CP	New Dosage Form	Denied Sep 24, 1985
Tri-Phasic Contraceptive Tablet; Oral(21 and 28 days)		84 P-0443/CP	New Strength (Dose Schedule)	Denied Sep 3, 1985
Ethinyl Estradiol Norethindrone	0.05mg 0.5mg			
Ethinyl Estradiol Norethindrone	0.05mg 0.75mg			
Ethinyl Estradiol Norethindrone	0.05mg 1.0mg			
Fluphenazine Hydrochloride Injectable; Injection	5mg/ml	85 P-0019/CP	New Strength	Denied Oct 25, 1985
Heparin Sodium Injectable; Injection	2000 Units/ml	85 P-0065/CP	New Strength	Denied May 29, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Heparin Sodium Injectable; Injection	4000 Units/ml	85 P-0065/CP	New Strength	Denied May 29, 1985
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release; Oral	50mg 80mg 75mg	85 P-0571/CP	New Combination	Denied May 16, 1986
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release; Oral	50mg 120mg 75mg	85 P-0571/CP	New Combination	Denied May 16, 1986
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release;	50mg 160mg 75mg	85 P-0571/CP	New Combination	Denied May 16, 1986
Ibuprofen; Oxycodone Hydrochloride Capsule; Oral Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Ibuprofen; Oxycodone Hydrochloride Tablet; Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985
Indomethacin Tablet; Oral	25mg	85 P-0025/CP	New Dosage Form	Denied Mar 31, 1986
Indomethacin Tablet; Oral	50mg	85 P-0025/CP	New Dosage Form	Denied Mar 31, 1986
Indomethacin Intensol Solution (Concentrate);	50mg/ml	85 P-0077/CP	New Dosage Form New Strength	Denied Apr 7, 1986
Indomethacin Tablet, Constant Release; Oral	75mg	85 P-0026/CP	New Dosage Form	Denied Sep 16, 1985
Indomethacin Controlled-release Tablet; Oral	75mg	85 P-0180/CP	New Dosage Form	Denied Apr 7, 1986
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml 50ml/vial	86 P-0015/CP	New Strength	Denied Apr 25, 1986

(continued)

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml 75ml/vial	86 P-0015/CP	New Strength	Denied Apr 25, 1986
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml 100ml/vial	86 P-0015/CP	New Strength	Denied Apr 25, 1986
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0062/CP	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0457/CP	New Strength	Denied Apr 18, 1986
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0062/ CP0002	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0457/ CP0002	New Strength	Denied Apr 18, 1986
Metronidazole Sponge; Vaginal	50-125mg/ Sponge	85 P-0117/CP	New Dosage Form	Denied Oct 8, 1985
Nitroglycerin Transdermal System	None Given	84 P-0302/CP	New Dosage Form (New Matrix)	Denied Jul 29, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Phenylephrine Hydrochloride; Sulfathiazole Nasal Suspension; Topical	0.5% 5%	85 P-0205/CP	New Dosage Form New Combination	Denied Nov 14, 1985
Pseudoephedrine Polisterex Controlled Release Capsule; Oral	60mg	85 P-0334/CP	New Salt New Ingredient	Denied Mar 19, 1986
Triamcinolone Acetonide Suspension; Injection	2.5mg/ml	85 P-0001/CP	New Strength	Denied Mar 4, 1985
Triamcinolone Acetonide Suspension; Injection	3mg/ml	84 P-0240/CP	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
D-6	SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE
D-7	BID DOSING

(continued)

APPENDIX 5

(continued)

NEW DOSING SCHEDULE

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
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

(continued)

APPENDIX 5

(continued)

NEW INDICATION

	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
	I-39	ADJUVANT WITH CHEMOTHERAPY FOR TREATMENT OF BREAST CANCER FOLLOWING MASTECTOMY
	I-40	ANTIDOTE FOR ACETAMINOPHEN OVERDOSE
	I-41	MANAGEMENT OF HYPOCALCEMIA AND RESULTANT METABOLIC BONE DISEASE IN RENAL DIALYSIS PATIENTS
>ADD>	I-42	MAINTENANCE THERAPY AT REDUCED DOSE FOLLOWING HEALING OF ACUTE DUODENAL ULCER
>ADD>	I-43	TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE

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 - MAY 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		
13601 001			I-40	JAN 31, 1988
13601 002			I-40	JAN 31, 1988
/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/		
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		
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	/NS/	/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/		
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		

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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		
17970 001	4536516	AUG 20, 2002	I-39	DEC 10, 1988
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
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/		
18154 001	3461461	MAY 07, 1985		
/18154/003/	/3461461/	/AUG/12;/1986/		
18154 003	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
>DLT>	/18257/001/	/4237068/	/DEC/02;/1997/	
>ADD>	18257 001	4237068	NOV 09, 1998	
>DLT>	18257 002	/4237068/	/DEC/02;/1997/	
>ADD>	18257 002	4237068	NOV 09, 1998	
	18401 001	3433791	MAR 18, 1986	
	18423 001	3855140	DEC 17, 1991	
		3960745	DEC 17, 1991	
>ADD>	18471 001		NDF	MAY 30, 1989
	18482 001	3784684	JAN 08, 1991	
	18506 001	/3419565/	/DEC/31;/1985/	
		/3717647/	/FEB/20;/1996/	
	18509 001		NP	AUG 07, 1988
	18513 002		ODE	JUL 28, 1990
	18587 003	3658993	APR 25, 1989	NCE SEP 07, 1992
	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	

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	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
	18677 001	4087545	MAY 02, 1995	NCE	DEC 26, 1990
		4087547	MAY 02, 1995		
	18683 001	4393871	JUL 19, 2000		
	18701 001	3438991	APR 15, 1986	NE	JAN 14, 1989
> ADD >	18703 001			I-42	MAY 30, 1989
> ADD >	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
> ADD >				I-42	MAY 30, 1989
> ADD >				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/		
	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
	18754 002	3641127	FEB 08, 1989	NCE	JAN 09, 1991
	18754 003	3641127	FEB 08, 1989	NCE	JAN 09, 1991
	18813 001	/3839573/	/OCT/01,/1991/		
	18827 001	/3839573/	/OCT/01,/1991/		
	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
	18859 001	4211771	JUL 08, 1997	NCE	DEC 31, 1990
		RE29835	MAR 19, 1991		

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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		
18887 001	3686412	AUG 22, 1989	NDF	DEC 05, 1988
	3777033	AUG 22, 1989		
18891 001	4559222	DEC 17, 2002		
18891 002	4559222	DEC 17, 2002		
18891 003	4559222	DEC 17, 2002		
18928 001	4221778	SEP 09, 1997		
18932 001			ODE	NOV 20, 1991
18948 001			NCE	DEC 27, 1990
			ODE	DEC 27, 19920
18949 001	/3806526/	/APR/23,/1991/		
	/3965257/	/JUN/22,/1993/		
	/3966649/	/JUN/29,/1993/		
	/4254129/	/MAR/03,/1998/		
	/4285957/	/AUG/25,/1998/		
18956 001	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998		
18956 002	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998		
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
18985 001	4544554	JUL 23, 2002		
18985 002	4544554	JUL 23, 2002		
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
19011 001			NP	SEP 24, 1986
/19044/001/	/4335059/	/JUN/15,/1999/	/NCE/	/DEC/23,/1996/

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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	/4335095/	/OCT/01/1991/		
19071 001			ODE	AUG 30, 1992
			NP	AUG 30, 1988
19079 001			NE	FEB 11, 1989
19084 001	4335125	JUN 15, 1999	NDF	DEC 31, 1988
19107 001			NCE	OCT 17, 1990
19107 001			ODE	OCT 17, 1992
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
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		
19322 001	3721687	MAR 20, 1990	NCE	DEC 27, 1990
19323 001	3721687	MAR 20, 1990	NCE	DEC 27, 1990
19359 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990
19368 001	4205086	MAY 27, 1997	NCE	OCT 29, 1990
			ODE	OCT 29, 1992
19412 001			NS	MAR 10, 1989
19412 002			NS	MAR 10, 1989
19412 003			NS	MAR 10, 1989
19412 004			NS	MAR 10, 1989

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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
19478 001	3644627	FEB 22, 1989		
	3784684	JAN 08, 1991		

*REFER TO APPENDIX I NARRATIVE