CUMULATIVE SUPPLEMENT 8
AUG'85-APR'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

APRIL 1986

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*New Section

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CUMULATIVE SUPPLEMENT

APRIL 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

3. PREDNISONE BIOEQUIVALENCE

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

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

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

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

4. OTC DRUG PRODUCTS

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

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

5. PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

Products	Federal Register Reference
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
DRUG PRODUCTS LISTED	8048	8230	8515
SINGLE SOURCE	2096 (26.0%)	2100 (25.5%)	2144 (25.1%)
MULTISOURCE(1)	5952 (74.0%)	6130 (74.5%)	6371 (74.9%)
THERAPEUTICALLY EQUIVALENT	4864 (60.5%)	5034 (61.2%)	5263 (61.8%)
NOT THERAPEUTICALLY EQUIVALENT	1054 (13.1%)	1058 (12.9%)	1070 (12.6%)
EXCEPTIONS(2)	34 (0.4%)	38 (0.4%)	38 (0.5%)
NEW MOLECULAR ENTITIES APPROVED	-	5	21
NUMBER OF APPLICANTS	306	313	322

B. ACTIVITY FOR SUPPLEMENT NUMBER 8

	FEB '86	MAR '86	APR '86	CUMULATIVE
DRUG PRODUCTS ADDED:	59	61	70	190
NEWLY APPROVED	59	61	70	190
DESI EFFECTIVE	0	0	0	0
REMARKETED	0	0	0	0
DRUG PRODUCTS REMOVED:	0	0	0	0
WITHDRAWN APPROVAL	0	0	0	0
RX TO OTC SWITCH	0	0	0	0
NET GAIN IN DRUG PRODUCTS	59	61	70	190
SINGLE SOURCE PRODUCTS APPROVED	6	9	16	31
MULTISOURCE DRUG PRODUCTS APPROVED	53	52	54	159
NEW MOLECULAR ENTITIES APPROVED:	0	1	0	1
AS THE ENTITY	0	1	0	1
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	0	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

	REID-ROWELL	356.4MG;30MG;16MG*	N88584 001	MAR 04, 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; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL
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

ACETAMINOPHEN AND CODEINE PHOSPHATE #4

AA	MIKART	300MG;60MG*	N89244 001	FEB 25, 1986
AA	SUPERPHARM	300MG;60MG*	N89185 001	OCT 18, 1985

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

TABLET; ORAL
DURADYNE DHC

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

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	> ADD >
			MAR 21, 1986	> ADD >
AB	CORD LABORATORIES	650MG;100MG¤	N70443 001	> ADD >
			JAN 23, 1986	> ADD >
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	> ADD >
			AUG 21, 1985	> ADD >
				> ADD >

ACYCLOVIR (PAGE 3-5)

CAPSULE; ORAL
ZOVIRAX

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

ALLOPURINOL (PAGE 3-6)

TABLET; ORAL
ALLOPURINOL

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

ALLOPURINOL (PAGE 3-6)

TABLET; ORAL
ALLOPURINOL

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
MIDAMOR

AB	MS&D/MERCK	5MG	N18200 001

AMILORIDE HCL

AB	PAR PHARMACEUTICAL	5MG¤	N70346 001
			JAN 22, 1986

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; 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

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

> ADD > INJECTABLE; INJECTION
> ADD > AMINOSYN II 7% W/ ELECTROLYTES
> ADD > ABBOTT LABORATORIES 7%;102MG/100ML;45MG/100ML;
> ADD > 522MG/100ML;410MG/100ML* N19437 006
> ADD > APR 03, 1986
> ADD > AMINOSYN II 8.5% W/ ELECTROLYTES
> ADD > ABBOTT LABORATORIES 8.5%;102MG/100ML;45MG/100ML;
> ADD > 522MG/100ML;410MG/100ML* N19437 005
> ADD > APR 03, 1986
> ADD > AMINOSYN II 10% W/ ELECTROLYTES
> ADD > ABBOTT LABORATORIES 10%;102MG/100ML;45MG/100ML;
> ADD > 522MG/100ML;410MG/100ML* N19437 004
> ADD > 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

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

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
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
LANORINAL

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

TABLET; ORAL
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

> ADD > AP	ABBOTT LABORATORIES	50MG/ML¤	N19033 001	APR 29, 1986 : APR 16, 1986
AP	INTL MEDICATION SYS	50MG/ML¤	N70119 001	APR 29, 1986 : MAR 06, 1986
AP	LYPHOMED	50MG/ML¤	N70134 001	APR 29, 1986 : FEB 12, 1986

BRETYLIUM TOSYLATE IN PLASTIC CONTAINER

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

BRETYLOL

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

> ADD > BRETYLIUM TOSYLATE; DEXTROSE (PAGE 3-28)

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE IN DEXTROSE 5%

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

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

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

> DLT > /~~CALCIFEDIOL, ANHYDROUS~~ (PAGE 3-31)
> ADD > 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

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

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

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

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

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

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

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

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

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

> ADD >
> ADD >
> ADD >
> ADD >

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

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION

	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
	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
> ADD > SK&F LAB — 800MG¤ — N17920 005
> ADD > — 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
> ADD > AA UPJOHN — EQ 75MG BASE/5ML¤ — N62644 001
> ADD > — APR 07, 1986
> ADD > 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
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

> ADD >	AP	BRISTOL LABS/B-M	2GM/VIAL	N12142 005	AUG 30, 1982
> ADD >		**LYOPHILIZED CYTOXAN**			
> ADD >	AP	BRISTOL LABS/B-M	100MG/VIAL¤	N12142 006	DEC 05, 1985
> ADD >	AP		200MG/VIAL¤	N12142 007	DEC 10, 1985
> ADD >	AP		500MG/VIAL¤	N12142 008	JAN 04, 1984
> ADD >	AP		1GM/VIAL¤	N12142 010	SEP 24, 1985
> ADD >	AP		2GM/VIAL¤	N12142 009	DEC 10, 1984

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-62)

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

> ADD >	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

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

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 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	
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	

DIAZEPAM (PAGE 3-72)

TABLET; ORAL
DIAZEPAM

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	

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	

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

DOXYCYCLINE HYCLATE (PAGE 3-79)

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

TABLET; ORAL
DOXYCYCLINE

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

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

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 3-89)

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

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

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

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

EPINEPHRINE (PAGE 3-81)

INJECTABLE; INJECTION
SUS-PHRINE
/BERLEX/SCHERING/ /5MG/ML/ /N07942.001/
FOREST LABORATORIES 5MG/ML N07942 001

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

FLUOCINOLONE ACETONIDE (PAGE 3-92)

SOLUTION; TOPICAL
FLUOCINOLONE ACETONIDE
AT THAMES PHARMACAL 0.01%* N89124 001
SEP 11, 1985

FLUOROMETHOLONE (PAGE 3-93)

OINTMENT; OPHTHALMIC
FML
ALLERGAN PHARMS 0.1%* N17760 001
SEP 04, 1985

SUSPENSION/DROPS; OPHTHALMIC
FLUOR-OP
AB COOPERVISION PHARMS 0.1%* N70185 001
FEB 27, 1986

FML
AB ALLERGAN PHARMS 0.1% N16851 002
JUL 28, 1982

>ADD< FML FORTE
>ADD< ALLERGAN PHARMS 0.25%* N19216 001
>ADD< 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

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
AP		EQ 1.2MG BASE/ML;9MG/ML*	N62588 001 JAN 06, 1986
AP		EQ 1.4MG BASE/ML;9MG/ML*	N62588 002 JAN 06, 1986
AP		EQ 1.6MG BASE/ML;9MG/ML*	N62588 003 JAN 06, 1986
AP		EQ 1.8MG BASE/ML;9MG/ML*	N62588 004 JAN 06, 1986
AP		EQ 2MG BASE/ML;9MG/ML*	N62588 005 JAN 06, 1986

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
>ADD > AA NATL PHARM MFG/BARRE EQ 2MG BASE/ML✖ N70318 001
>ADD > APR 15, 1986 : APR 11, 1986

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION
/HEP-LOCK PF/
/AP/ /ELKINS-SINN/AHROBINS/10 UNITS/ML/ /N17037 010/
/JUN 10, 1983/
/AP/ /100 UNITS/ML/ /N17037 011/
/JUN 10, 1983/
HEP-LOCK U/P
AP ELKINS-SINN/AHROBINS 10 UNITS/ML N17037 010
JUN 10, 1983
AP 100 UNITS/ML N17037 011
JUN 10, 1983
HEPARIN 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
>ADD > ABBOTT LABORATORIES 2,000 UNITS/ML✖ N05264 013
>ADD > APR 07, 1986
>ADD > AP 2,500 UNITS/ML✖ N05264 014
>ADD > APR 07, 1986

HEPARIN SODIUM (PAGE 3-103)

HEPARIN SODIUM
/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
>ADD > AP ELKINS-SINN/AHROBINS 5,000 UNITS/0.5ML✖ N17037 013
>ADD > APR 07, 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/

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

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

INJECTABLE; INJECTION
HYDRALAZINE HCL
AP SOLOPAK LABORATORIES 20MG/ML✖ N88517 001
AUG 22, 1985

TABLET; ORAL
HYDRALAZINE HCL
AA HALSEY DRUG 10MG✖ N89218 001
JAN 22, 1986
AA 25MG✖ N89130 001
JAN 15, 1986
AA 50MG✖ N89222 001
JAN 22, 1986
AA 100MG✖ N89178 001
JAN 15, 1986
AA 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
>ADD> AB		25MG;250MG¤	N70366 001	APR 16, 1986
>ADD> AB		30MG;500MG¤	N70367 001	MAR 19, 1986
>ADD> 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
>ADD> AB	PUREPAC/KALIPHARMA	25MG;250MG¤	N70688 001	APR 24, 1986
>ADD> AB		50MG;500MG¤	N70689 001	APR 24, 1986

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE (PAGE 3-111)

TABLET; ORAL

INDERIDE-40/25

>ADD> AB	AYERST LABS/AMHO	25MG;40MG	N18031 001	

INDERIDE-80/25

>ADD> AB	AYERST LABS/AMHO	25MG;80MG	N18031 002	

PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

>ADD> AB	CHELSEA LABORATORIES	25MG;40MG¤	N70301 001	APR 18, 1986
>ADD> AB		25MG;80MG¤	N70305 001	APR 18, 1986

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

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

/HYDROCODONE;.PHENYLTOLOXAMINE.(PAGE.3-112)/

/SUSPENSION;.ORAL/

/TUSSIONEX/

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

HYDROCORTISONE (PAGE 3-112)

CREAM; TOPICAL

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

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
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

IBUPROFEN (PAGE 3-120)

TABLET; ORAL

	IBUPROFEN			
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
AB	ə PAR PHARMACEUTICALS	300MG¤	N70328 001	AUG 06, 1985
AB		400MG¤	N70329 001	AUG 06, 1985
AB		600MG¤	N70330 001	AUG 06, 1985
>ADD> AB	SUPERPHARM	400MG¤	N70708 001	APR 25, 1986
>ADD> AB		600MG¤	N70709 001	APR 25, 1986
	IBUPROHM			
AB	OHM LABORATORIES	400MG¤	N70469 001	AUG 29, 1985
	MOTRIN			
AB	ə UPJOHN	300MG	N17463 003	
		800MG¤	N17463 005	MAY 22, 1985

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

INDOMETHACIN (PAGE 3-122)

CAPSULE; ORAL

	INDOMETHACIN			
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

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

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
ə LEDERLE LABS/AM CYAN EQ 10MG BASE N17525 006
ə EQ 25MG BASE N17525 007
ə 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
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

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

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION
FOLEX PFS

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

METHOTREXATE LPF

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

METHOTREXATE SODIUM

AP	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
> ADD > AB	PARKE-DAVIS/W-L	125MG¤	N70331 001 APR 15, 1986
> ADD > AB		250MG¤	N70332 001 APR 15, 1986
> ADD > AB		500MG¤	N70333 001 APR 15, 1986

METHYLDOPA (PAGE 3-144)

TABLET; ORAL
METHYLDOPA

	AB	PUREPAC/KALIPHARMA	125MG¤	N70749 001	FEB 07, 1986
	AB		250MG¤	N70750 001	FEB 07, 1986
	AB		500MG¤	N70452 001	FEB 07, 1986
>ADD<	AB	ROXANE LABORATORIES	125MG¤	N70192 001	APR 25, 1986
>ADD<	AB		250MG¤	N70193 001	APR 25, 1986
>ADD<	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

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION
REGLAN

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

TABLET; ORAL
CLOPRA-"YELLOW"

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

MAXOLON

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

METOCLOPRAMIDE HCL

	AB	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

>ADD<	AP	CARTER-GLOGAU LABS	500MG/100ML¤	N70170 001	
>ADD<					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

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

METRYL 500

/ADD/	/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
> ADD > NALOXONE HCL
> ADD > AP WINTHROP-BREON/STERL 0.02MG/ML¤ N70171 001
> ADD > SEP 24, 1986 : APR 18, 1986
> ADD > AP 0.4MG/ML¤ N70172 001
> ADD > SEP 24, 1986 : APR 18, 1986
NARCAN
AP DUPONT PHARMS/DUPONT 0.02MG/ML N16636 002
AP 0.4MG/ML N16636 001
/P/ 1MG/ML N16636 003
JUN 14, 1982

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE (PAGE 3-151)

TABLET; ORAL
TALWIN NX
/WINTHROP-BREON/STERL/0.5MG;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
> ADD > AT BURROUGHS WELLCOME EQ 40MG BASE/ML; 200,000 UNITS/ML N60707 001
> ADD > NEOMYCIN AND POLYMYXIN B SULFATES
> ADD > AT CARTER-GLOGAU LABS EQ 40MG BASE/ML; 200,000 UNITS/ML¤ N62664 001 APR 08, 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/
/S/HOECHST-ROUSSEL/ /25MG/ /N18224 001/ /DEC 31, 1984/
/S/ /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

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

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			
>ADD>	∂ 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			
>ADD> AA	DURAMED PHARMS	30MG¤	N88948 001	APR 25, 1986
>ADD> 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~~	~~N60905 001~~	
~~BX~~	~~ZENITH LABORATORIES~~	~~100MG~~	~~N60259 001~~	

PHENYTOIN SODIUM, PROMPT (PAGE 3-169)

CAPSULE; ORAL
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

>ADD>	◑ ABBOTT LABORATORIES	6GM/100ML;75MG/100ML;168MG/100ML; 146MG/100ML; 1.29GM/100ML¤		N19284 001
>ADD>				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

>ADD> BC	A/S BENZON	10MEQ¤		N19381 001
>ADD>				APR 16, 1986

KLOR-CON

>ADD> BC	UPSHER-SMITH LABS	8MEQ¤		N19123 001
>ADD>				APR 17, 1986
>ADD> BC		10MEQ¤		N19123 002
>ADD>				APR 17, 1986

SLOW-K

>ADD> 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

/**PROTOPAM**/

/AP/	/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

PREDNISONE (PAGE 3-176)

TABLET; ORAL
DELTASONE

AB	UPJOHN	5MG		N09986 002
AB		10MG		N09986 006
AB		20MG		N09986 007

PREDNISONE

AB	MUTUAL PHARM	5MG¤		N89245 001
				DEC 04, 1985
AB		10MG¤		N89246 001
				DEC 04, 1985
AB		20MG¤		N89247 001
				DEC 04, 1985
/BX/	/DURAMED PHARMS/	/20MG/		/N88396 001/
AB	DURAMED PHARMS	20MG		N88396 001
				OCT 04, 1983
/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
> ADD >	AP	ELKINS-SINN/AHROBINS	100MG/ML*	N89029 001 APR 17, 1986
> ADD >				
> ADD >	AP		500MG/ML*	N89030 001 APR 17, 1986
> ADD >				
AP		PHARMAFAIR	100MG/ML*	N88824 001 NOV 20, 1985
AP			500MG/ML*	N88830 001 NOV 20, 1985

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

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

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 HCL		
AB		BARR LABORATORIES	10MG*	N70319 001 OCT 22, 1985
AB			20MG*	N70320 001 OCT 22, 1985
AB			40MG*	N70103 001 OCT 22, 1985
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
> ADD >	AB	PAR PHARMACEUTICAL	80MG*	N70221 001 APR 14, 1986
> ADD >				
> ADD >	AB	WATSON LABS	20MG*	N70549 001 APR 11, 1986
> ADD >				
> ADD >	AB		40MG*	N70550 001 APR 11, 1986
> ADD >				

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
>DLT< /KABIVITRUM/ /75CU/VIAL/ /N18290 001/
>ADD< 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/
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
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
/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
> ADD > AB	COLMED LABORATORIES	250MG¤	N70168 001 APR 02, 1986
> ADD > 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

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

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

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

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

AP		QUAD PHARMS	2.5MG/ML		N70672 001 MAR 07, 1986

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

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

>ADD>	AP	ELI LILLY	1MG/ML		N14103 003 MAR 07, 1984

VINCRISTINE SULFATE

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

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
2.5%* N19421 001 DEC 17, 1985

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-225)

CAPSULE, CONTROLLED RELEASE; ORAL
ISOCLOR
AM CRITICAL CARE/AHS 8MG;120MG* N18747 001 MAR 06, 1986

> ADD >
CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX (PAGE 3-225)
> ADD >
> ADD >

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

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
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 ZINC SUSPENSION, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION
HUMULIN L
ELI LILLY 100 UNITS/ML* N19377 002 SEP 30, 1985

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 - APRIL 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.

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

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 18B-31, 5600 Fishers Lane, Rockville, MD 20857.

Name of Drug	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
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
Dissolution Testing (General)	Apr 19, 1983
Doxepin Hydrochloride	Apr 02, 1985
Erythromycin	Apr 05, 1977

(continued)

*New Addition

APPENDIX 3

(continued)

Name of Drug	Date
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
Verapamil	Jul 1985

*New Addition

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	Docket Number	Reason for Petition	Status
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	Docket Number	Reason for Petition	Status
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
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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength	Docket Number	Reason for Petition	Status
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
Benztropine Mesylate Syrup; Oral	0.5mg/5ml	85 P-0423/CP	New Dosage Form	Approved Oct 16, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength	Docket Number	Reason for Petition	Status
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)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength	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	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	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	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	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	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	Docket Number	Reason for Petition	Status
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	100mcg/ml	86 P-0099/CP	New Strength	Approved Apr 1, 1986
Nitroglycerin in 5% Dextrose Injectable; Injection	200mcg/ml	86 P-0099/CP CP0002	New Strength	Approved Apr 1, 1986
Nitroglycerin in 5% Dextrose Injectable; Injection	400mcg/ml	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	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	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
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	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	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	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	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	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	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	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) Ethinyl Estradiol Norethindrone Ethinyl Estradiol Norethindrone Ethinyl Estradiol Norethindrone	 0.05mg 0.5mg 0.05mg 0.75mg 0.05mg 1.0mg	84 P-0443/CP	New Strength (Dose Schedule)	Denied Sep 3, 1985
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	Docket Number	Reason for Petition	Status
Heparin Sodium Injectable; Injection	4000 Units/ml	85 P-0065/CP	New Strength	Denied May 29, 1985
Ibuprofen; Oxycodone Hydrochloride Capsule; Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985
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); Oral	50mg/ml	85 P-0077/CP	New Dosage Form New Strength	Denied Apr 7, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength	Docket Number	Reason for Petition	Status
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
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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength	Docket Number	Reason for Petition	Status
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
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

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength	Docket Number	Reason for Petition	Status
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
>ADD> 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

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 - APRIL ACTIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
>DLT>	/12142/001/	/4537883/	/AUG/27,/2002/		
>DLT>	/12142/002/	/4537883/	/AUG/27,/2002/		
>DLT>	/12142/003/	/4537883/	/AUG/27,/2002/		
>DLT>	/12142/004/	/4537883/	/AUG/27,/2002/		
>DLT>	/12142/005/	/4537883/	/AUG/27,/2002/		
>ADD>	12142 006	4537883	AUG 27, 2002		
>ADD>	12142 007	4537883	AUG 27, 2002		
>ADD>	12142 008	4537883	AUG 27, 2002		
>ADD>	12142 009	4537883	AUG 27, 2002		
>ADD>	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	

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	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		
	17785 001			NDF	MAR 07, 1989
>ADD>	17862 001	4536386	AUG 20, 2002	I-12	SEP 24, 1986
>ADD>				I-13	SEP 24, 1986
>ADD>				I-14	SEP 24, 1986
>ADD>	17862 002	4536386	AUG 20, 2002	I-12	SEP 24, 1986
>ADD>				I-13	SEP 24, 1986
>ADD>				I-14	SEP 24, 1986
>ADD>	17862 003	4536386	AUG 20, 2002	I-12	SEP 24, 1986
>ADD>				I-13	SEP 24, 1986
>ADD>				I-14	SEP 24, 1986
>ADD>	17920 005	3950333	APR 13, 1993	D-12	APR 30, 1989
>ADD>		4024271	MAY 17, 1994		

(continued)

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	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		
>_ADD_>	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
	18401 001	3433791	MAR 18, 1986		
	18423 001	3855140	DEC 17, 1991		
		3960785	DEC 17, 1991		
	18482 001	3784684	JAN 08, 1991		
	18506 001	/3419565/	/DEC/31;/1985/		
		/3717647/	/FEB/20;/1990/		
	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		
	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		

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
18701 001	3438991	APR 15, 1986	NE	JAN 14, 1989
18703 002	4128658	DEC 05, 1995	NCE	JUN 09, 1993
	4521431	JUN 04, 2002	I-15	JUN 28, 1988
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		
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

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
18949 001	/3806526/	/APR/23,/1991/		
	/3965257/	/JUN/22,/1993/		
	/3966949/	/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,/1990/
19044 001	4335095	JUN 15, 1999	NCE	DEC 23, 1990
19059 001	4138475	FEB 06, 1996	**PETITION FOR EXCLUSIVITY PENDING**	
19059 002	4138475	FEB 06, 1996	**PETITION FOR EXCLUSIVITY PENDING**	
19059 003	4138475	FEB 06, 1996	**PETITION FOR EXCLUSIVITY PENDING**	
19069 001	/3839573/	/OCT/01,/1991/		
19071 001			ODE	AUG 30, 1992
			NP	AUG 30, 1988
19079 001			NE	FEB 11, 1989
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

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
> ADD >	19257 001			NDF	APR 10, 1989
> ADD >				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
	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

(continued)

SUBSCRIPTION FORM

APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 6TH EDITION (1985)

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Superintendent of Documents
Government Printing Office
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