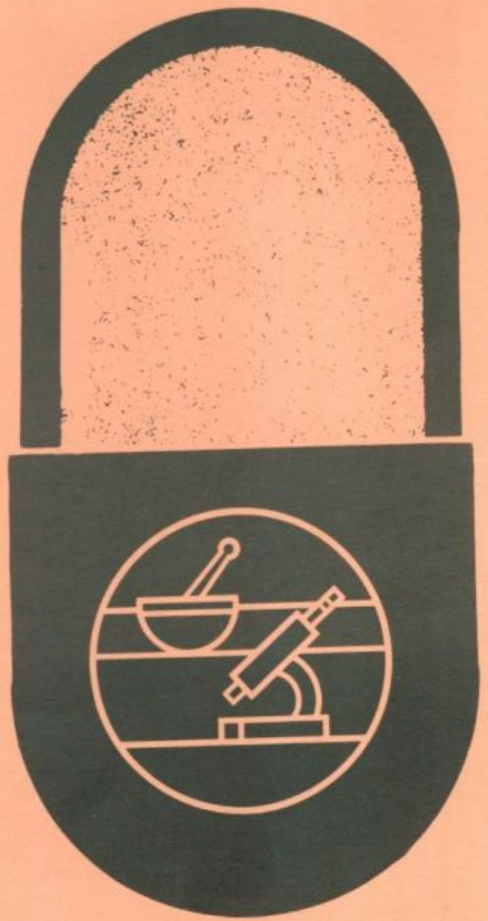
CUMULATIVE SUPPLEMENT 10 AUG'85-JUN'86



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

JUNE 1986

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A. INTRODUCTION

1. HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 6th Edition (the List). The List is comprised of three drug product lists: The Prescription Drug Product list, the OTC Drug Product list, and the Drug Products Approved Under Section 505 of the Act by the Division of Blood and Blood Products list. The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Information in the Cumulative Supplement follows the format of the drug product lists. The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

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

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

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

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

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

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

2. APPLICANT (NAME) CHANGES

Because it is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this Special Notes section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement. The current list of applicant holder changes follows.

APPLICANT (NAME) CHANGES

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

(continued)

APPLICANT (NAME) CHANGES

(continued)

Former Applicant (Name)	New Applicant (Name)	New Abbreviated Name
AM MCGAW/AM HOSP	KENDALL MCGAW LABORATORIES, INC	KENDALL MCGAW LABS
IVES LABS/AMHO	WYETH LABORATORIES; INC DIVISION OF AMERICAN HOME PRODUCTS CORP	WYETH LABS/AMHO
REID PROVIDENT LABS AND ROWELL LABORATORIES	REID-ROWELL	REID-ROWELL
BAY LABORATORIES	MY-K LABORATORIES, INC	MY-K LABS

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	APR '86
DRUG PRODUCTS LISTED	8048	8230	8515	8683
SINGLE SOURCE	2096 (26.0%)	2100 (25.5%)	2144 (25.1%)	2138 (24.6%)
MULTISOURCE(1)	5952 (74.0%)	6130 (74.5%)	6371 (74.9%)	6545 (75.4%)
THERAPEUTICALLY EQUIVALENT	4864 (60.5%)	5034 (61.2%)	5263 (61.8%)	5422 (62.5%)
NOT THERAPEUTICALLY EQUIVALENT	1054 (13.1%)	1058 (12.9%)	1070 (12.6%)	1068 (12.3%)
EXCEPTIONS(2)	34 (0.4%)	38 (0.4%)	38 (0.5%)	55 (0.6%)
NEW MOLECULAR ENTITIES APPROVED	-	5	21	1
NUMBER OF APPLICANTS	306	313	322	324

B. ACTIVITY FOR SUPPLEMENT NUMBER 10

	MAY '86	JUNE '86	CUMULATIVE
DRUG PRODUCTS ADDED:	60	59	119
NEWLY APPROVED	57	56	113
DESI EFFECTIVE	0	3	3
REMARKETED	3	0	3
DRUG PRODUCTS REMOVED:	0	0	0
WITHDRAWN APPROVAL	0	0	0
RX TO OTC SWITCH	0	0	0
NET GAIN IN DRUG PRODUCTS	60	59	119
SINGLE SOURCE PRODUCTS APPROVED	5	9	14
MULTISOURCE DRUG PRODUCTS APPROVED	55	50	105
NEW MOLECULAR ENTITIES APPROVED:	0	0	0
AS THE ENTITY	0	0	0
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	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
AA REID-ROWELL 356.4MG;30MG;16MG* N88584 001 MAR 04, 1986

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

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

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

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

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

ACETAMINOPHEN AND CODEINE PHOSPHATE #3
AA MIKART 300MG;30MG* N89238 001 FEB 25, 1986
AA SUPERPHARM 300MG;30MG* N89184 001 OCT 18, 1985
AA 300MG;30MG* N89253 001 MAY 19, 1986

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

ACETAMINOPHEN W/ CODEINE
/AA/ /VITARINE/ /300MG;30MG/ /N85917.001/

ACETAMINOPHEN W/ CODEINE #2
/AA/ /VITARINE/ /300MG;15MG/ /N87433.001/

ACETAMINOPHEN W/ CODEINE #4
/AA/ /VITARINE/ /300MG;60MG/ /N87423.001/

PHENAPHEN-650 W /CODEINE
AA AH ROBINS 650MG;30MG N85856 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

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

BANCAP HC
AA FOREST PHARM/FOREST 500MG;5MG N87961 001 MAR 17, 1983
/AA/ /O'NEAL,JONES&FELDMAN//500MG;5MG/ /N87961.001/ /MAR.17,.1983/

HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA MIKART 500MG;5MG* N89008 001 FEB 21, 1986

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

TABLET; ORAL

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

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL

	PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN			
AB	BARR LABORATORIES	650MG;100MG¤	N70615 001	MAR 21, 1986
AB		650MG;100MG¤	N70771 001	MAR 21, 1986
AB		650MG;100MG¤	N70775 001	MAR 21, 1986
AB	CORD LABORATORIES	650MG;100MG¤	N70443 001	JAN 23, 1986
AB	LEMMON	650MG;100MG¤	N70732 001	JAN 03, 1986
AB	ZENITH LABORATORIES	650MG;100MG¤	N70146 001	AUG 02, 1985

ACETAZOLAMIDE (PAGE 3-4)

TABLET; ORAL

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

ACETIC ACID, GLACIAL (PAGE 3-4)

SOLUTION/DROPS; OTIC

	BOROFAIR			
AT	PHARMAFAIR	2%¤	N88606 001	AUG 21, 1985

ACYCLOVIR (PAGE 3-5)

CAPSULE; ORAL

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

ALLOPURINOL (PAGE 3-6)

TABLET; ORAL

	ALLOPURINOL			
AB	BARR LABORATORIES	100MG¤	N70466 001	NOV 30, 1988 : DEC 24, 1985
AB		300MG¤	N70467 001	NOV 30, 1988 : DEC 24, 1985
AB	CORD LABORATORIES	100MG¤	N70268 001	/NOV 30, 1988 : DEC 31, 1985
AB		300MG¤	N70269 001	/NOV 30, 1988 : DEC 31, 1985
AB	PAR PHARMACEUTICAL	100MG¤	N70150 001	/NOV 30, 1988 : DEC 10, 1985
AB		300MG¤	N70147 001	/NOV 30, 1988 : DEC 10, 1985
AB	PUREPAC/KALIPHARMA	100MG¤	N70579 001	APR 14, 1986
AB		300MG¤	N70580 001	APR 14, 1986

AMILORIDE HYDROCHLORIDE (PAGE 3-7)

TABLET; ORAL

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

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION

AMINOSYN-PF 7%			
ABBOTT LABORATORIES	7%¤	N19398 001	SEP 06, 1985
AMINOSYN II 3.5%			
ABBOTT LABORATORIES	3.5%¤	N19438 001	APR 03, 1986
AMINOSYN II 5%			
ABBOTT LABORATORIES	5%¤	N19438 002	APR 03, 1986
AMINOSYN II 7%			
ABBOTT LABORATORIES	7%¤	N19438 003	APR 03, 1986
AMINOSYN II 8.5%			
ABBOTT LABORATORIES	8.5%¤	N19438 004	APR 03, 1986
AMINOSYN II 10%			
ABBOTT LABORATORIES	10%¤	N19438 005	APR 03, 1986

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

INJECTABLE; INJECTION

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

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

INJECTABLE; INJECTION
AMINOSYN II 3.5% M
ABBOTT LABORATORIES 3.5%;32MG/100ML;128MG/100ML; 222MG/100ML;49MG/100ML* N19437 007 APR 03, 1986

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

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

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

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

AMINOCAPROIC ACID (PAGE 3-9)

INJECTABLE; INJECTION
AMINOCAPROIC ACID

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

AMINOPHYLLINE (PAGE 3-10)

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

AMIODARONE HYDROCHLORIDE (PAGE 3-11)

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

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

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

AMOXICILLIN (PAGE 3-15)

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

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

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

AMPICILLIN SODIUM (PAGE 3-17)

INJECTABLE; INJECTION

AMPICILLIN SODIUM

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

TOTACILLIN-N

> ADD >	AP	BEECHAM LABS/BEECHAM	EQ 10GM BASE/VIAL	N60677 001

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

BUTALBITAL W/ ASPIRIN AND CAFFEINE

AB	CHELSEA LABORATORIES	325MG;50MG;40MG	N86231 002 FEB 12, 1985
	FIORINAL		
AB	SANDOZ PHARMS/SANDOZ	325MG;50MG;40MG*	N17534 005 APR 16, 1986
	LANORINAL		
AB	LANNETT	325MG;50MG;40MG*	N86996 002 OCT 11, 1985

TABLET; ORAL

BUTALBITAL W/ ASPIRIN AND CAFFEINE

> ADD >	AB	WEST-WARD	325MG;50MG;40MG	N86162 002 FEB 16, 1984
> ADD >				
		FIORINAL		
	AB	SANDOZ PHARMS/SANDOZ	325MG;50MG;40MG*	N17534 003 APR 16, 1986
		LANORINAL		
	AB	LANNETT	325MG;50MG;40MG*	N86986 002 OCT 18, 1985

ASPIRIN; CARISOPRODOL (PAGE 3-20)

TABLET; ORAL

CARISOPRODOL COMPOUND

AB	BOLAR PHARMACEUTICAL	325MG;200MG*	N88809 001	OCT 03, 1985

SOMA COMPOUND

AB	WALLACE PHARMS/C-W	325MG;200MG	N12365 005	JUL 11, 1983

ASPIRIN; 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

BENZYL PENICILLOYL-POLYLYSINE (PAGE 3-25)

INJECTABLE; INJECTION

PRE-PEN

>DLT>	/KREMERS-URBAN/	/60 UMOLAR/	/N50114 001/	
>ADD>	SCHWARZ PHARMS	60 UMOLAR	N50114 001	

BETAMETHASONE BENZOATE (PAGE 3-25)

CREAM; TOPICAL

>DLT>	/BENISONE/			
>DLT>	/PARKE-DAVIS/W-L/	/0.25%/	/N16998 001/	
>ADD>	UTICORT			
>ADD>	PARKE-DAVIS/W-L	0.25%	N16998 002	

BETAMETHASONE BENZOATE (PAGE 3-25)

GEL; TOPICAL

>DLT>	/BENISONE/			
>ADD>	UTICORT			

OINTMENT: TOPICAL

>DLT>	/BENISONE/			
>ADD>	UTICORT			

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

CREAM; TOPICAL

DIPROLENE

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

LOTION; TOPICAL

ALPHATREX

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

BETAMETHASONE DIPROPIONATE

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

BETAMETHASONE VALERATE (PAGE 3-26)

CREAM; TOPICAL

BETAMETHASONE VALERATE

>ADD>	AB	CLAY-PARK LABS	EQ 0.1% BASE*	N70053 001	
>ADD>				JUN 10, 1986	

OINTMENT; TOPICAL

BETA-VAL

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

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC

BETOPTIC

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

BETHANECHOL CHLORIDE (PAGE 3-27)

TABLET; ORAL
BETHANECHOL CHLORIDE

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

BRETYLIUM TOSYLATE (PAGE 3-28)

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE

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

BRETYLIUM TOSYLATE IN PLASTIC CONTAINER

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

BRETYLOL

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

BRETYLIUM TOSYLATE; DEXTROSE (PAGE 3-28)

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE IN DEXTROSE 5%

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

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

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

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-29)

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

BUPIVACAINE HYDROCHLORIDE (PAGE 3-29)

INJECTABLE; INJECTION
SENSORCAINE

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

BUPIVACAINE HYDROCHLORIDE; DEXTROSE (PAGE 3-29)

INJECTABLE; INJECTION
MARCAINE SPINAL

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

BUPROPION HYDROCHLORIDE (PAGE 3-30)

TABLET; ORAL
WELLBUTRIN

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

BUTOCONAZOLE NITRATE (PAGE 3-31)

CREAM; VAGINAL
FEMSTAT

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

SUPPOSITORY; VAGINAL
FEMSTAT

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

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

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

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

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

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

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

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

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

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

INJECTABLE; INJECTION
IPN ELECTROLYTES IN PLASTIC CONTAINER
> ADD > AP ABBOTT LABORATORIES 16.5MG/ML;25.4MG/ML;74.6MG/ML; 121MG/ML;16.1MG/ML* N19399 001 JUN 16, 1986
> ADD > AP 16.5MG/ML;25.4MG/ML;74.6MG/ML; 121MG/ML;16.1MG/ML N18895 001 JUL 20, 1984

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

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

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

CARBACHOL (PAGE 3-36)

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

MIOSTAT
AP ALCON LABORATORIES 0.01% N16968 001

CARBAMAZEPINE (PAGE 3-36)

TABLET; ORAL

CARBAMAZEPINE

AB	COLMED LABORATORIES	200MG¤	N70300 001 MAY 15, 1986

TEGRETOL

AB	GEIGY/CIBA-GEIGY	200MG	N16608 001

CARNITINE, L- (PAGE 3-37)

SOLUTION; ORAL

VITACARN

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

TABLET; ORAL

> DLT > /L-CARNITINE/

> ADD > CARNITOR

	SIGMA-TAU	330MG¤	N18948 001 DEC 27, 1985

CEFAMANDOLE NAFATE (PAGE 3-37)

INJECTABLE; INJECTION

MANDOL

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

CEFAZOLIN SODIUM (PAGE 3-38)

INJECTABLE; INJECTION

KEFZOL

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

CEFOTETAN DISODIUM (PAGE 3-38)

INJECTABLE; INJECTION

CEFOTAN

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

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION

FORTAZ

AP	GLAXO	500MG/VIAL	N50578 001 JUL 19, 1985
AP		1GM/VIAL	N50578 002 JUL 19, 1985
AP		2GM/VIAL	N50578 003 JUL 19, 1985
AP		6GM/VIAL	N50578 004 JUL 19, 1985

TAZICEF

AP	SK&F LABORATORIES	500MG/VIAL¤	N62662 001 MAR 06, 1986
AP		1GM/VIAL¤	N62662 002 MAR 06, 1986
AP		2GM/VIAL¤	N62662 003 MAR 06, 1986
AP		6GM/VIAL¤	N62662 004 MAR 06, 1986

TAZIDIME

AP	ELI LILLY	500MG/VIAL¤	N62640 001 NOV 20, 1985
AP		1GM/VIAL¤	N62640 002 NOV 20, 1985
AP		1GM/VIAL¤	N62655 001 NOV 20, 1985
AP		2GM/VIAL¤	N62655 002 NOV 20, 1985
AP		2GM/VIAL¤	N62640 003 NOV 20, 1985

CEFUROXIME SODIUM (PAGE 3-40)

INJECTABLE; INJECTION

KEFUROX

AP	ELI LILLY	EQ 750MG BASE/VIAL¤	N62591 001 JAN 10, 1986
AP		EQ 750MG BASE/VIAL¤	N62592 001 JAN 10, 1986
AP		EQ 1.5GM BASE/VIAL¤	N62591 002 JAN 10, 1986
AP		EQ 1.5GM BASE/VIAL¤	N62592 002 JAN 10, 1986

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)

> ADD > CHROMIC CHLORIDE (PAGE 3-50)

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	

> ADD > CHROMIC CHLORIDE (PAGE 3-50)

> ADD > INJECTABLE; INJECTION
> ADD > CHROMIC CHLORIDE IN PLASTIC CONTAINER

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

CILASTATIN SODIUM; IMIPENEM (PAGE 3-50)

INJECTABLE; INJECTION
PRIMAXIN

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

CIMETIDINE (PAGE 3-50)

TABLET; ORAL
TAGAMET

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

CIMETIDINE HYDROCHLORIDE; SODIUM CHLORIDE (PAGE 3-50)

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

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

CLINDAMYCIN PALMITATE HYDROCHLORIDE (PAGE 3-51)

POWDER FOR RECONSTITUTION; ORAL
CLEOCIN

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

CLOBETASOL PROPIONATE (PAGE 3-51)

CREAM; TOPICAL
TEMOVATE

	GLAXO	0.05%¤	N19322 001 DEC 27, 1985	

OINTMENT; TOPICAL
TEMOVATE

	GLAXO	0.05%¤	N19323 001 DEC 27, 1985	

CLOFIBRATE (PAGE 3-51)

CAPSULE; ORAL

		ATROMID-S			
> ADD >	AB	AYERST LABS/AMHO	500MG		N16099 002
> ADD >		**CLOFIBRATE**			
> ADD >	AB	FORMUTEC	500MG*		N70531 001
> ADD >					JUN 16, 1986

CLONAZEPAM (PAGE 3-52)

TABLET; ORAL

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

CLONIDINE HYDROCHLORIDE (PAGE 3-52)

TABLET; ORAL

		CATAPRES			
AB		BOEHRINGER INGELHEIM	0.1MG		N17407 001
AB			0.2MG		N17407 002
AB			0.3MG		N17407 003
		CLONIDINE HCL			
AB		AM THERAPEUTICS	0.1MG*		N70881 001
				JUL 08, 1986 : MAY 27, 1986	
AB			0.2MG*		N70882 001
				JUL 08, 1986 : MAY 27, 1986	
AB			0.3MG*		N70883 001
				JUL 08, 1986 : MAY 27, 1986	
AB		BIOCRAFT LABS	0.1MG*		N70747 001
				JUL 08, 1986 : MAR 20, 1986	
AB			0.2MG*		N70702 001
				JUL 08, 1986 : MAR 20, 1986	
AB			0.3MG*		N70659 001
				JUL 08, 1986 : MAR 20, 1986	
AB		PAR PHARMACEUTICAL	0.1MG*		N70461 001
				JUL 08, 1986 : NOV 22, 1985	
AB			0.2MG*		N70460 001
				JUL 08, 1986 : NOV 22, 1985	
AB			0.3MG*		N70459 001
				JUL 08, 1986 : NOV 22, 1985	

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

SYRUP; ORAL

		PROMETHAZINE VC W/ CODEINE			
AA		HR CENCI LABS	10MG/5ML;5MG/5ML; 6.25MG/5ML*		N88816 001
					NOV 22, 1985

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-53)

SYRUP; ORAL

		PROMETHAZINE W/ CODEINE			
AA		HR CENCI LABS	10MG/5ML;6.25MG/5ML*		N88814 001
					NOV 22, 1985

COPPER (PAGE 3-54)

INTRAUTERINE DEVICE; INTRAUTERINE

		CU-7			
		◕ SEARLE PHARMS	89MG		N17408 001
		TATUM-T			
		◕ SEARLE PHARMS	120MG		N18205 001

CROMOLYN SODIUM (PAGE 3-55)

AEROSOL; INHALATION

		INTAL			
		FISONS	0.8MG/INH*		N18887 001
					DEC 05, 1985

CYCLOPHOSPHAMIDE (PAGE 3-57)

INJECTABLE; INJECTION

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

> ADD > CUPRIC CHLORIDE (PAGE 3-55)

> ADD > INJECTABLE; INJECTION

> ADD > CUPRIC CHLORIDE IN PLASTIC CONTAINER

> ADD >		ABBOTT LABORATORIES	EQ 0.4MG COPPER/ML*		N18960 001
> ADD >					JUN 26, 1986

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-62)

INJECTABLE; INJECTION

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

SYRUP; ORAL

PROMETHAZINE VC W/ CODEINE

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

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-62)

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

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

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)

TABLET; ORAL

DEXCHLORPHENIRAMINE MALEATE

AB SIDMAK LABORATORIES 2MG* N88682 001 JAN 17, 1986

POLARAMINE

AB SCHERING 2MG N86835 001

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION

DEXTROSE 5% IN PLASTIC CONTAINER

AP ABBOTT LABORATORIES 5GM/100ML* N19479 001 SEP 17, 1985

AP TRAVENOL LABS 50MG/ML* N16673 003 OCT 30, 1985

DEXTROSE 50% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABORATORIES 500MG/ML* N19445 001 JUN 03, 1986
> ADD >

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION

LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

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

INJECTABLE; INJECTION

IONOSOL B AND DEXTROSE 5% IN PLASTIC CONTAINER

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

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

INJECTABLE; INJECTION

IONOSOL MB AND DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 5GM/100ML;30MG/100ML;141MG/100ML; 15MG/100ML;260MG/100ML; 25MG/100ML* N19513 001 MAY 08, 1986

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

INJECTABLE; INJECTION

IONOSOL T AND DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 5GM/100ML;111MG/100ML;256MG/100ML; 146MG/100ML;207MG/100ML* N19514 001 MAY 08, 1986

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

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 5GM/100ML;74.5MG/100ML; 300MG/100ML* N18876 001 JAN 17, 1986

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 5GM/100ML;149MG/100ML; 300MG/100ML* N18876 002 JAN 17, 1986

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.224% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 5GM/100ML;224MG/100ML; 300MG/100ML* N18876 003 JAN 17, 1986

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER

AP KENDALL MCGAW LABS 5GM/100ML;75MG/100ML; 330MG/100ML* N18268 011 JAN 18, 1986

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER

AP KENDALL MCGAW LABS 5GM/100ML;150MG/100ML; 330MG/100ML* N18268 012 JAN 18, 1986

DEXTROSE 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
>ADD> AP	LYPHOMED	5MG/ML¤	N70662 001	JUN 25, 1986

VALIUM

AP	HOFFMANN-LA ROCHE	5MG/ML	N16087 001	

TABLET; ORAL

DIAZEPAM

AB	BARR LABORATORIES	2MG¤	N70152 001	NOV 01, 1985
AB		5MG¤	N70153 001	NOV 01, 1985
AB		10MG¤	N70154 001	NOV 01, 1985

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

DIAZEPAM

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
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
>ADD> AB	ROXANE LABORATORIES	2MG¤	N70356 001	JUN 17, 1986
>ADD> AB		5MG¤	N70357 001	JUN 17, 1986
>ADD> AB		10MG¤	N70358 001	JUN 17, 1986

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

		DIAZEPAM		
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)

CAPSULE; ORAL

		BENTYL		
>ADD>	AB	MERRELL DOW/DOW CHEM	10MG	N07409 001 OCT 15, 1984
		DICYCLOMINE HCL		
>ADD>	AB	BOLAR PHARMACEUTICAL	10MG¤	N83179 001 FEB 12, 1986
>ADD>				
>ADD>	AB	CHELSEA LABORATORIES	10MG¤	N85082 001 JUN 19, 1986
>ADD>				

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
>ADD>	AB	BOLAR PHARMACEUTICAL	20MG¤	N84361 001 FEB 06, 1986
>ADD>				

DIFLORASONE DIACETATE (PAGE 3-74)

CREAM; TOPICAL

		DIFLORASONE DIACETATE		
BX		UPJOHN	0.05%¤	N19259 001 AUG 28, 1985
		FLORONE		
BX		UPJOHN	0.05%	N17741 001

OINTMENT; TOPICAL

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

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-76)

CAPSULE; ORAL

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

DISOPYRAMIDE PHOSPHATE (PAGE 3-77)

CAPSULE; ORAL

		DISOPYRAMIDE PHOSPHATE		
AB		BARR LABORATORIES	EQ 100MG BASE¤	N70351 001 DEC 17, 1985
AB			EQ 150MG BASE¤	N70352 001 DEC 17, 1985
AB		BOLAR PHARMACEUTICAL	EQ 100MG BASE¤	N70240 001 FEB 02, 1986
AB			EQ 150MG BASE¤	N70241 001 FEB 02, 1986
AB		CORD LABORATORIES	EQ 100MG BASE¤	N70470 001 DEC 10, 1985
AB			EQ 150MG BASE¤	N70471 001 DEC 10, 1985
AB		ZENITH LABORATORIES	EQ 100MG BASE¤	N70186 001 NOV 18, 1985
AB			EQ 150MG BASE¤	N70187 001 NOV 18, 1985

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION

DOPAMINE HCL

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

DOPASTAT

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

INTROPIN

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

DOXEPIN HYDROCHLORIDE (PAGE 3-78)

CAPSULE ORAL

DOXEPIN HCL

AB	CHELSEA LABORATORIES	EQ 25MG BASE*	N70953 001	MAY 15, 1986
AB		EQ 50MG BASE*	N70954 001	MAY 15, 1986
AB		EQ 100MG BASE*	N70955 001	MAY 15, 1986
AB	CORD LABORATORIES	EQ 25MG BASE*	N70827 001	MAY 15, 1986
AB		EQ 50MG BASE*	N70828 001	MAY 15, 1986
AB		EQ 75MG BASE*	N70825 001	MAY 15, 1986

DOXEPIN HYDROCHLORIDE (PAGE 3-78)

CAPSULE ORAL

DOXEPIN HCL

AB	MYLAN PHARMS	EQ 10MG BASE*	N70789 001	MAY 13, 1986
AB		EQ 25MG BASE*	N70790 001	MAY 13, 1986
AB		EQ 50MG BASE*	N70791 001	MAY 13, 1986
AB		EQ 75MG BASE*	N70792 001	MAY 13, 1986
AB		EQ 100MG BASE*	N70793 001	MAY 13, 1986

DOXYCYCLINE HYCLATE (PAGE 3-79)

CAPSULE, COATED PELLETS; ORAL

DORYX

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

CAPSULE; ORAL

/**DORYX**/

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

DOXYCYCLINE HYCLATE

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

INJECTABLE; INJECTION

DOXYCYCLINE

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

DOXYCYCLINE HYCLATE

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

DOXYCYCLINE HYCLATE (PAGE 3-79)

TABLET; ORAL
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

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

TESTOSTERONE CYPIONATE-ESTRADIOL CYPIONATE

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

ESTROGEN, CONJUGATED (PAGE 3-86)

TABLET; ORAL
CONJUGATED ESTROGENS

>DLT>	/BS/	/ICN PHARMACEUTICALS/	/0.3MG/	/N86491 001/
>DLT>	/BS/		/0.625MG/	/N83272 001/
>DLT>	/BS/		/1.25MG/	/N83294 001/
>DLT>	/BS/		/2.5MG/	/N83295 001/
>ADD>	BS	DURAMED PHARM	0.3MG	N86492 001
>ADD>	BS		0.625MG	N83272 001
>ADD>	BS		1.25MG	N83294 001
>ADD>	BS		2.5MG	N83295 001

ESTROGEN, CONJUGATED; MEPROBAMATE (PAGE 3-87)

TABLET; ORAL
PMB 200
/BS/ /AYERST LABS/AMHO/ /0.4MG;200MG/ /N10971 005/
BS AYERST LABS/AMHO 0.45MG;200MG N10971 005
PMB 400
/BS/ /AYERST LABS/AMHO/ /0.4MG;400MG/ /N10971 003/
BS AYERST LABS/AMHO 0.45MG;400MG N10971 003

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 3-89)

TABLET; ORAL-21
ORTHO-NOVUM 7/14-21
◕ ORTHO PHARMACEUTICAL 0.035MG;0.5MG AND 1MG N19004 001
APR 04, 1984

TABLET; ORAL-28
ORTHO-NOVUM 7/14-28
◕ ORTHO PHARMACEUTICAL 0.35MG;0.5MG AND 1MG N19004 002
APR 04, 1984

ETHOXZOLAMIDE (PAGE 3-90)

TABLET; ORAL
ETHAMIDE
◕ ALLERGAN PHARMS 125MG N16144 001

FLECAINIDE ACETATE (PAGE 3-92)

TABLET; ORAL
TAMBOCOR
RIKER LABS/3M 100MG✱ N18830 001
OCT 31, 1985
200MG✱ N18830 002
OCT 31, 1985

FLUNISOLIDE (PAGE 3-92)

AEROSOL; INHALATION
/BRONALIDE/
/SYNTEX LABS/SYNTEX/ /0.025MG/INH/ /N18340 001/
/AUG 17, 1984/
AEROBID
KEY PHARMACEUTICALS 0.025MG/INH N18340 001
AUG 17, 1984

FLUOCINOLONE ACETONIDE (PAGE 3-92)

SOLUTION; TOPICAL
FLUOCINOLONE ACETONIDE
AT THAMES PHARMACAL 0.01½✱ N89124 001
SEP 11, 1985

FLUOROMETHOLONE (PAGE 3-93)

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

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

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

FML FORTE
ALLERGAN PHARMS 0.25%✱ N19216 001
APR 23, 1986

FLUOROMETHOLONE ACETATE (PAGE 3-93)

SUSPENSION/DROPS; OPHTHALMIC
OMNITROL
ALCON LABORATORIES 0.1%✱ N19079 001
FEB 11, 1986

FLUOROURACIL (PAGE 3-93)

INJECTABLE; INJECTION
FLUOROURACIL
AP INTL PHARM PROD 50MG/ML✱ N88929 001
MAR 04, 1986
AP LYPHOMED 50MG/ML✱ N89152 001
MAR 21, 1986

FLUPHENAZINE DECANOATE (PAGE 3-94)

INJECTABLE; INJECTION
FLUPHENAZINE
AO QUAD PHARMS 25MG/ML✱ N70762 001
FEB 20, 1986

PROLIXIN DECANOATE
AO ER SQUIBB AND SONS 25MG/ML N16727 001

FLUPHENAZINE HYDROCHLORIDE (PAGE 3-94)

CONCENTRATE; ORAL

	PERMITIL		
AA	SCHERING	5MG/ML	N16008 001
	PROLIXIN		
AA	ER SQUIBB AND SONS	5MG/ML*	N70533 001 NOV 07, 1985

FLURAZEPAM HYDROCHLORIDE (PAGE 3-95)

CAPSULE; ORAL

	DALMANE		
AB	ROCHE PRODUCTS	15MG	N16721 001
AB		30MG	N16721 002
	FLURAZEPAM HCL		
AB	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 (PAGE 3-102)

TABLET; ORAL

HALDOL

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

HALOPERIDOL

> ADD > AB	MYLAN PHARMS	0.5MG¤		N70276 001 JUN 10, 1986
> ADD > AB		1MG¤		N70277 001 JUN 10, 1986
> ADD > AB		2MG¤		N70278 001 JUN 10, 1986
> ADD > AB		5MG¤		N70279 001 JUN 10, 1986
> ADD > AB	SEARLE PHARMS	0.5MG¤		N70720 001 JUN 10, 1986
> ADD > AB		1MG¤		N70721 001 JUN 10, 1986
> ADD > AB		2MG¤		N70722 001 JUN 10, 1986
> ADD > AB		5MG¤		N70723 001 JUN 10, 1986
> ADD > AB		10MG¤		N70724 001 JUN 10, 1986
> ADD > AB		20MG¤		N70725 001 SEP 24, 1986 : JUN 10, 1986

HALOPERIDOL DECANOATE (PAGE 3-102)

INJECTABLE; INJECTION

HALDOL DECANOATE

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

HALOPERIDOL LACTATE (PAGE 3-102)

CONCENTRATE; ORAL

HALDOL

AA	MCNEIL LABORATORIES	EQ 2MG BASE/ML	N15922 001

HALOPERIDOL

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

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION

HEP-LOCK U/P

AP	ELKINS-SINN/AHROBINS	10 UNITS/ML	N17037 010 JUN 10, 1983
AP		100 UNITS/ML	N17037 011 JUN 10, 1983

HEPARIN LOCK FLUSH

AP	CARTER-GLOGAU LABS	100 UNITS/ML	N17064 001
AP	LUITPOLD PHARMS	10 UNITS/ML¤	N89063 001 OCT 09, 1985
AP		100 UNITS/ML¤	N89064 001 OCT 09, 1985

HEPARIN SODIUM

	ABBOTT LABORATORIES	2,000 UNITS/ML¤	N05264 013 APR 07, 1986
AP		2,500 UNITS/ML¤	N05264 014 APR 07, 1986
AP	CARTER-GLOGAU LABS	100 UNIT/ML	N17064 001
AP		2,500 UNITS/ML	N17064 015
AP		7,500 UNITS/ML	N17064 019
		3,000 UNITS/ML	N17064 016
		4,000 UNITS/ML	N17064 017
		6,000 UNTIS/ML	N17064 018
AP	ELKINS-SINN/AHROBINS	5,000 UNITS/0.5ML¤	N17037 013 APR 07, 1986

HEPARIN SODIUM PRESERVATIVE FREE

AP	INVENEX/LYPHOMED	1,000 UNITS/ML¤	N17029 010 APR 28, 1986
> ADD > AP	MARSAM	1,000 UNITS/ML¤	N89464 001 JUN 03, 1986
> ADD >			

LIQUAEMIN SODIUM PRESERVATIVE FREE

AP	ORGANON/AKZONA	1,000 UNITS/ML¤	N00552 011 APR 11, 1986
AP		5,000 UNITS/ML¤	N00552 012 APR 11, 1986
AP		10,000 UNITS/ML¤	N00552 013 APR 11, 1986

SODIUM HEPARIN

AP	CARTER-GLOGAU LABS	2,500 UNITS/ML	N17064 015
AP		7,500 UNITS/ML	N17064 019
		3,000 UNITS/ML	N17064 016
		4,000 UNITS/ML	N17064 017
		6,000 UNITS/ML	N17064 018

HEXACHLOROPHENE (PAGE 3-106)

SPONGE; TOPICAL

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

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

INJECTABLE; INJECTION

HYDRALAZINE HCL

AP	SOLOPAK LABORATORIES	20MG/ML¤	N88517 001 AUG 22, 1985

TABLET; ORAL

HYDRALAZINE HCL

AA	HALSEY DRUG	10MG¤	N89218 001 JAN 22, 1986
AA		25MG¤	N89130 001 JAN 15, 1986
AA		50MG¤	N89222 001 JAN 22, 1986
AA		100MG¤	N89178 001 JAN 15, 1986
AA	MUTUAL PHARM	25MG¤	N89258 001 MAY 05, 1986
AA		50MG¤	N89259 001 MAY 05, 1986
AA	SIDMAK LABORATORIES	10MG¤	N89097 001 DEC 18, 1985
AA		100MG¤	N89098 001 DEC 18, 1985

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-108)

CAPSULE; ORAL

HYDRA-ZIDE

AB	PAR PHARMACEUTICAL	25MG;25MG¤	N88957 001 OCT 21, 1985
AB		50MG;50MG¤	N88946 001 OCT 21, 1985
AB		100MG;50MG¤	N88961 001 OCT 21, 1985

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)

TABLET; ORAL

	ALDORIL D30			
AB	MS&D/MERCK	30MG;500MG	N13402 003	
	ALDORIL D50			
AB	MS&D/MERCK	50MG;500MG	N13402 004	
	ALDORIL 15			
AB	MS&D/MERCK	15MG;250MG	N13402 001	
	ALDORIL 25			
AB	MS&D/MERCK	25MG;250MG	N13402 002	
	METHYLDOPA AND HYDROCHLOROTHIAZIDE			
AB	BOLAR PHARMACEUTICAL	15MG;250MG*	N70365 001	MAR 19, 1986
AB		25MG;250MG*	N70366 001	APR 16, 1986
AB		30MG;500MG*	N70367 001	MAR 19, 1986
AB		50MG;500MG*	N70368 001	APR 16, 1986
AB	CORD LABORATORIES	15MG;250MG*	N70182 001	JAN 15, 1986
AB		25MG;250MG*	N70183 001	JAN 15, 1986
AB		30MG;500MG*	N70543 001	JAN 15, 1986
AB		50MG;500MG*	N70544 001	JAN 15, 1986
AB	MYLAN PHARMS	15MG;250MG*	N70264 001	JAN 23, 1986
AB		25MG;250MG*	N70265 001	JAN 23, 1986
AB	PUREPAC/KALIPHARMA	25MG;250MG*	N70688 001	APR 24, 1986
AB		50MG;500MG*	N70689 001	APR 24, 1986

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE (PAGE 3-111)

TABLET; ORAL

	INDERIDE-40/25			
AB	AYERST LABS/AMHO	25MG;40MG	N18031 001	
	INDERIDE-80/25			
AB	AYERST LABS/AMHO	25MG;80MG	N18031 002	
	PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE			
AB	CHELSEA LABORATORIES	25MG;40MG*	N70301 001	APR 18, 1986
AB		25MG;80MG*	N70305 001	APR 18, 1986
AB	PUREPAC/KALIPHARMA	25MG;40MG*	N70851 001	MAY 15, 1986
AB		25MG;80MG*	N70852 001	MAY 15, 1986

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL

	SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE			
AB	PUREPAC/KALIPHARMA	25MG;25MG*	N87999 001	NOV 06, 1985
AB	SUPERPHARM	25MG;25MG*	N89137 001	AUG 26, 1985

/HYDROCODONE; PHENYLTOLOXAMINE (PAGE 3-112)/

/SUSPENSION; ORAL/

	/TUSSIONEX/			
	/PENNWALT PHARM/	/EQ 5MG BASE/5ML;/ /EQ 10MG BASE/5ML/	/N10768 006/	

HYDROCORTISONE (PAGE 3-112)

CREAM; TOPICAL

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

LOTION; TOPICAL

	HYDROCORTISONE			
AT	THAMES PHARMACAL	1%*	N89024 001	FEB 12, 1986
	STIE-CORT			
AT	STIEFEL LABORATORIES	1%*	N89066 001	NOV 25, 1985
AT		2.5%*	N89074 001	NOV 26, 1985

OINTMENT; TOPICAL

	HYDROCORTISONE IN ABSORBASE			
AT	CAROLINA MED PRODS	1%*	N88138 001	SEP 06, 1985

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

SUSPENSION; OTIC

	NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE			
AT	CARTER-GLOGAU LABS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML*	N62488 001	NOV 06, 1985
	NEOMYCIN SULFATE, POLYMYXIN B SULFATE & HYDROCORTISONE			
AT	PHARMAFAIR	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML*	*N62617 001*	*SEP 18, 1985*

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

SUSPENSION/DROPS; OPHTHALMIC

CORTISPORIN

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

NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE

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

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

CREAM; TOPICAL

CORTISPORIN

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

HYDROCORTISONE BUTYRATE (PAGE 3-116)

CREAM; TOPICAL

HYDROCORTISONE BUTYRATE

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

LOCOID

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

OINTMENT; TOPICAL

HYDROCORTISONE BUTYRATE

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

LOCOID

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

HYDROFLUMETHIAZIDE; RESERPINE (PAGE 3-117)

TABLET; ORAL

HYDROFLUMETHIAZIDE AND RESERPINE

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

HYDROXYZINE HYDROCHLORIDE (PAGE 3-118)

INJECTABLE; INJECTION

HYDROXYZINE

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

HYDROXYZINE HCL

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

TABLET; ORAL

HYDROXYZINE HCL

AB	COLMED LABORATORIES	10MG*	N89121 001	MAR 20, 1986
AB		25MG*	N89122 001	MAR 20, 1986
AB		50MG*	N89123 001	MAR 20, 1986

HYDROXYZINE HCL

AB	MUTUAL PHARM	10MG*	N89381 001	MAY 19, 1986
AB		25MG*	N89382 001	MAY 19, 1986
AB		50MG*	N89383 001	MAY 19, 1986
AB	QUANTUM PHARMICS	10MG*	N88540 001	OCT 22, 1985
AB		25MG*	N88551 001	OCT 22, 1985
AB		50MG*	N88529 001	OCT 22, 1985
AB	SIDMAK LABORATORIES	10MG*	N88617 001	JAN 10, 1986
AB		25MG*	N88618 001	JAN 10, 1986
AB		50MG*	N88619 001	JAN 10, 1986

HYDROXYZINE PAMOATE (PAGE 3-120)

CAPSULE; ORAL

HYDROXYZINE PAMOATE

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

IBUPROFEN (PAGE 3-120)

TABLET; ORAL

		IBUPROFEN			
	AB	CHELSEA LABORATORIES	400MG¤	N70038 001	SEP 06, 1985
	AB		600MG¤	N70041 001	SEP 06, 1985
> ADD >	AB	CORD LABORATORIES	300MG¤	N70734 001	JUN 12, 1986
> ADD >	AB		400MG¤	N70735 001	JUN 12, 1986
> ADD >	AB		600MG¤	N70736 001	JUN 12, 1986
	AB	DANBURY PHARMACAL	400MG¤	N70436 001	AUG 21, 1985
	AB		600MG¤	N70437 001	AUG 21, 1985
> ADD >	AB	MCNEIL CONSUMER PROD	400MG¤	N70081 001	JUN 16, 1986
> ADD >	AB		600MG¤	N70476 001	JUN 16, 1986
	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	/℘/PAR PHARMACEUTICALS	300MG¤	N70328 001	AUG 06, 1985
	AB		400MG¤	N70329 001	AUG 06, 1985
	AB		600MG¤	N70330 001	AUG 06, 1985
	AB	SUPERPHARM	400MG¤	N70708 001	APR 25, 1986
	AB		600MG¤	N70709 001	APR 25, 1986
		IBUPROHM			
	AB	OHM LABORATORIES	400MG¤	N70469 001	AUG 29, 1985
		MOTRIN			
	AB	◕ UPJOHN	300MG	N17463 003	MAY 22, 1985
			800MG¤	N17463 005	

INDIUM IN-111 OXYQUINOLINE (PAGE 3-121)

INJECTABLE; INJECTION

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

INDOMETHACIN (PAGE 3-122)

CAPSULE; ORAL

	INDO-LEMMON			
AB	LEMMON	25MG¤	N70266 001	NOV 07, 1985
AB		50MG¤	N70267 001	NOV 07, 1985
	INDOMETHACIN			
AB	DURAMED PHARMS	25MG¤	N70326 001	OCT 18, 1985
AB		50MG¤	N70327 001	OCT 18, 1985
AB	MYLAN PHARMS	50MG¤	N70624 001	SEP 04, 1985
AB	PAR PHARMACEUTICAL	50MG¤	N70651 001	MAR 05, 1986
AB	WATSON LABORATORIES	25MG¤	N70529 001	OCT 18, 1985
AB		50MG¤	N70530 001	OCT 18, 1985
AB	ZENITH LABORATORIES	25MG¤	N70719 001	FEB 12, 1986
AB		50MG¤	N70756 001	FEB 12, 1986

SUSPENSION; ORAL

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

IOHEXOL (PAGE 3-123)

INJECTABLE; INJECTION

	OMNIPAQUE 180			
	WINTHROP-BREON/STERL	38.8%¤	N18956 001	DEC 26, 1985
	OMNIPAQUE 240			
	WINTHROP-BREON/STERL	51.8%¤	N18956 002	DEC 26, 1985
	OMNIPAQUE 300			
	WINTHROP-BREON/STERL	64.7%¤	N18956 003	DEC 26, 1985
	OMNIPAQUE 350			
	WINTHROP-BREON/STERL	75.5%¤	N18956 004	DEC 26, 1985

IOPAMIDOL (PAGE 3-123)

INJECTABLE; INJECTION

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

IOPAMIDOL (PAGE 3-123)

INJECTABLE; INJECTION
ISOVUE-370
ER SQUIBB AND SONS 76%* N18735 003 DEC 31, 1985

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

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

ISONIAZID (PAGE 3-125)

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

KANAMYCIN SULFATE (PAGE 3-126)

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

KETOCONAZOLE (PAGE 3-127)

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

KETOPROFEN (PAGE 3-127)

CAPSULE; ORAL
ORUDIS
WYETH LABS/AMHO 50MG* N18754 002 JAN 09, 1986
75MG* N18754 003 JAN 09, 1986

LABETALOL HYDROCHLORIDE (PAGE 3-127)

INJECTABLE; INJECTION
NORMODYNE
AP SCHERING 5MG/ML N18686 001 AUG 01, 1984

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

LACTULOSE (PAGE 3-127)

SYRUP; ORAL
LACTULOSE
AA ROXANE LABORATORIES 10GM/15ML N17906 001

LEUCOVORIN CALCIUM (PAGE 3-127)

TABLET; ORAL
LEUCOVORIN CALCIUM
BX LEDERLE LABS/AM CYAN EQ 5MG BASE* N18459 001 JAN 30, 1986

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

LEVOBUNOLOL HYDROCHLORIDE (PAGE 3-128)

SOLUTION/DROPS; OPHTHALMIC
BETAGAN
ALLERGAN PHARMS 0.5%* N19219 002 DEC 19, 1985

LITHIUM CITRATE (PAGE 3-132)

SYRUP; ORAL
LITHIUM CITRATE
AA MY-K LABS EQ 300MG CARBONATE/5ML N70755 001 MAY 21, 1986

LORAZEPAM (PAGE 3-132)

TABLET; ORAL
ATIVAN
AB WYETH LABS/AMHO 0.5MG N17794 001
AB 1MG N17794 002
AB 2MG N17794 003

LORAZEPAM (PAGE 3-132)

TABLET; ORAL
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

> ADD > MANGANESE CHLORIDE (PAGE 3-134)

> ADD > INJECTABLE; INJECTION
> ADD > MANGANESE CHLORIDE IN PLASTIC CONTAINER

> ADD >	ABBOTT LABORATORIES	EQ 0.1MG MANGANESE/ML¤	N18962 001	JUN 26, 1986

MANNITOL (PAGE 3-134)

SOLUTION; IRRIGATION
RESECTISOL

/AM MCGAW/AM HOSP	/5GM/100ML/	/N16772/002/

RESECTISOL IN PLASTIC CONTAINER

AM MCGAW/AM HOSP	5GM/100ML	N16772 002

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

TABLET; ORAL
MECLIZINE HCL

AA	SIDMAK LABORATORIES	12.5MG¤	N88732 001	DEC 11, 1985
AA		25MG¤	N88733 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

MEDROXYPROGESTERONE ACETATE (PAGE 3-136)

TABLET; ORAL
PROVERA

UPJOHN	5MG	N11839 003

MENOTROPINS (PAGE 1-137)

INJECTABLE; INJECTION
PERGONAL

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

METHOCARBAMOL (PAGE 3-142)

TABLET; ORAL
METHOCARBAMOL

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

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION
FOLEX

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

FOLEX PFS

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

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION

	METHOTREXATE LPF				
AP	LEDERLE LABS/AM CYAN	EQ 25MG BASE/ML	N11719 007	MAR 31, 1982	
	METHOTREXATE SODIUM				
AP	INTL PHARM PRODS	EQ 25MG BASE/ML¤	N88648 001	MAY 09, 1986	
>ADD> AP	LYPHOMED	EQ 2.5MG BASE/ML¤	N89323 001	JUN 13, 1986	
>ADD> AP		EQ 20MG BASE/VIAL¤	N88935 001	OCT 11, 1985	
>ADD> AP		EQ 25MG BASE/ML¤	N89322 001	JUN 13, 1986	
>ADD> AP		EQ 25MG BASE/ML¤	N89263 001	JUN 13, 1986	
AP		EQ 50MG BASE/VIAL¤	N88936 001	OCT 11, 1985	
AP		EQ 100MG BASE/VIAL¤	N89937 001	OCT 11, 1985	
	METHOTREXATE				
>ADD> AP	LEDERLE LABS/AM CYAN	EQ 2.5MG BASE/ML	N11719 004		
	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	
>ADD> AB	DANBURY PHARMACAL	250MG¤	N70703 001	JUN 06, 1986	
>ADD> AB		500MG¤	N70625 001	JUN 06, 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	

METHYLDOPA (PAGE 3-144)

TABLET; ORAL

	METHYLDOPA				
AB	PARKE-DAVIS/W-L	125MG¤	N70331 001	APR 15, 1986	
AB		250MG¤	N70332 001	APR 15, 1986	
AB		500MG¤	N70333 001	APR 15, 1986	
AB	PUREPAC/KALIPHARMA	125MG¤	N70749 001	FEB 07, 1986	
AB		250MG¤	N70750 001	FEB 07, 1986	
AB		500MG¤	N70452 001	FEB 07, 1986	
AB	ROXANE LABORATORIES	125MG¤	N70192 001	APR 25, 1986	
AB		250MG¤	N70193 001	APR 25, 1986	
AB		500MG¤	N70194 001	APR 25, 1986	
AB	ZENITH LABORATORIES	250MG¤	N70098 001	FEB 20, 1986	
AB		500MG¤	N70343 001	FEB 20, 1986	

METHYLDOPATE HYDROCHLORIDE (PAGE 3-144)

INJECTABLE; INJECTION

	ALDOMET				
>ADD> AP	MS&D/MERCK	50MG/ML	N13401 001		
	METHYLDOPATE HCL				
>ADD> AP	LYPHOMED	50MG/ML¤	N70652 001	JUN 03, 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	

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-145)

INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

AP	LYPHOMED	EQ 40MG BASE/VIAL¤	N89143 001	MAR 28, 1986
AP		EQ 125MG BASE/VIAL¤	N89144 001	MAR 28, 1986
AP		EQ 500MG BASE/VIAL¤	N89186 001	MAR 28, 1986
AP		EQ 500MG BASE/VIAL¤	N89187 001	MAR 28, 1986
AP		EQ 1GM BASE/VIAL¤	N89188 001	MAR 28, 1986
AP		EQ 1GM BASE/VIAL¤	N89189 001	MAR 28, 1986

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

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

REGLAN

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

TABLET; ORAL

CLOPRA-"YELLOW"

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

MAXOLON

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

METOCLOPRAMIDE HCL

> ADD > AB	CHELSEA LABORATORIES	EQ 10MG BASE¤	N70453 001	JUN 06, 1986
> ADD > AB	DANBURY PHARMACAL	EQ 10MG BASE¤	N70511 001	JAN 22, 1986
AB	PAR PHARMACEUTICAL	EQ 10MG BASE¤	N70342 001	MAR 25, 1986
AB	PUREPAC/KALIPHARMA	EQ 10MG BASE¤	N70581 001	OCT 17, 1985

METRONIDAZOLE (PAGE 3-148)

INJECTABLE; INJECTION

METRONIDAZOLE

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

TABLET; ORAL

METRONIDAZOLE

AB	HALSEY DRUG	500MG¤	N70593 001	FEB 27, 1986
AB	VITARINE	250MG	N18620 001	MAR 04, 1982
AB		500MG	N18620 002	JUN 02, 1983

METRYL

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

METRYL 500

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

METRONIDAZOLE HYDROCHLORIDE (PAGE 3-148)

INJECTABLE; INJECTION

FLAGYL I.V.

AP	SEARLE PHARMS	EQ 500MG BASE/VIAL	N18353 001	

METRONIDAZOLE HCL

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

MEXILETINE HYDROCHLORIDE (PAGE 3-149)

CAPSULE; ORAL

MEXITIL

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

MIDAZOLAM HYDROCHLORIDE (PAGE 3-149)

INJECTABLE; INJECTION

VERSED

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

MONOOCTANOIN (PAGE 3-150)

LIQUID; PERFUSION, BILIARY
MOCTANIN

> DLT >	/ASCOT HOSP PHARMS/	/100%¤/		/N19368 001/ /OCT 29, 1985/
> ADD >	ETHITEK PHARMS	100%¤		N19368 001
> ADD >				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, 1988 :	MAR 28, 1986

NEGGRAM

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

NALOXONE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION
NALOXONE

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

NALOXONE HCL

AP	WINTHROP-BREON/STERL	0.02MG/ML¤		N70171 001
			SEP 24, 1986 :	APR 18, 1986
AP		0.4MG/ML¤		N70172 001
			SEP 24, 1986 :	APR 18, 1986

NARCAN

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

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE (PAGE 3-151)

TABLET; ORAL
TALWIN NX

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

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION
NANDROLONE DECANOATE

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

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION
NANDROLONE DECANOATE

> ADD > AO	QUAD PHARMS	50MG/ML¤	N89248 001	
> ADD >			JUN 25, 1986	
> ADD > AO		100MG/ML¤	N89249 001	
> ADD >			JUN 25, 1986	
> ADD > AO		200MG/ML¤	N89250 001	
> ADD >			JUN 25, 1986	

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

SOLUTION; IRRIGATION

NEOSPORIN G.U. IRRIGANT			
AT	BURROUGHS WELLCOME	EQ 40MG BASE/ML; 200,000 UNITS/ML	N60707 001
NEOMYCIN AND POLYMYXIN B SULFATES			
AT	CARTER-GLOGAU LABS	EQ 40MG BASE/ML; 200,000 UNITS/ML¤	N62664 001 APR 08, 1986

NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE (3-153)

OINTMENT; TOPICAL

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

NIFEDIPINE (PAGE 3-154)

CAPSULE; ORAL

ADALAT			
AB	MILES PHARM/MILES	10MG¤	N19478 001 NOV 27, 1985
PROCARDIA			
AB	PFIZER LABS/PFIZER	10MG	N18482 001

NITROGLYCERIN (PAGE 3-154)

AEROSOL; ORAL
NITROLINGUAL

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

NITROGLYCERIN (PAGE 3-154)

INJECTABLE; INJECTION
NITROGLYCERIN

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

/NOMIFENSINE MALEATE (PAGE 3-155)

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

NYSTATIN (PAGE 3-156)

POWDER; ORAL

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

SUSPENSION; ORAL
NYSTATIN

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

TABLET; ORAL
NYSTATIN

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

TABLET; VAGINAL
NYSTATIN

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

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

CREAM; TOPICAL

MYCO-TRIACET II

AT LEMMON 100,000 UNITS/GM;0.1%✱ N61954 002 SEP 20, 1985

MYTREX F

AT SAVAGE LABS/ALTANA 100,000 UNITS/GM;0.1%✱ N62597 001 OCT 08, 1985

NYSTATIN-TRIAMCINOLONE ACETONIDE

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

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

OINTMENT; TOPICAL

MYCO-TRIACET II

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

MYCOLOG-II

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

MYTREX F

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

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT CLAY-PARK LABS 100,000 UNITS/GM;0.1%✱ N62280 002 OCT 10, 1985

NYSTATIN-TRIAMCINOLONE ACETONIDE

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

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

OXYPHENBUTAZONE (PAGE 3-159)

TABLET; ORAL

OXYPHENBUTAZONE

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

PARGYLINE HYDROCHLORIDE (PAGE 3-160)

TABLET; ORAL

EUTONYL

⊜ ABBOTT LABORATORIES 50MG N13448 004

PENICILLIN G POTASSIUM (PAGE 3-161)

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN G POTASSIUM

AA ⊜ MYLAN PHARMS 200,000 UNITS/5ML N60752 003

AA ⊜ 250,000 UNITS/5ML N60752 002

AA ⊜ 400,000 UNITS/5ML N60752 001

PERMETHRIN (PAGE 3-164)

LOTION; TOPICAL

NIX

BURROUGHS WELLCOME 1%✱ N19435 001 MAR 31, 1986

PHENTERMINE HYDROCHLORIDE (PAGE 3-167)

CAPSULE; ORAL

~~ADIPEX~~

~~AA~~ ~~LEMMON~~ ~~30MG~~ N87126 001

PHENTERMINE HCL

AA DURAMED PHARMS 30MG✱ N88948 001 APR 25, 1986

AA LEMMON 30MG✱ N87777 001 NOV 01, 1985

AA 30MG N87126 001

PHENYLBUTAZONE (PAGE 3-168)

CAPSULE; ORAL

PHENYLBUTAZONE

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

TABLET; ORAL

PHENYLBUTAZONE

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

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-168)

SYRUP; ORAL

PROMETHAZINE VC PLAIN

AA HR CENCI LABS 5MG/5ML;6.25MG/5ML✱ N88815 001 NOV 22, 1985

PHENYTOIN SODIUM, EXTENDED (PAGE 3-169)

CAPSULE; ORAL

~~EXTENDED PHENYTOIN SODIUM~~

~~AB~~ ~~BOLAR PHARMACEUTICAL~~ ~~100MG~~ ~~N88711 001~~ ~~DEC 21, 1984~~

~~SETROL~~

PHENYTEX

AB BOLAR PHARMACEUTICAL 100MG N88711 001 DEC 21, 1984

PHENYTOIN SODIUM, PROMPT (PAGE 3-169)

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

PIPERAZINE CITRATE (PAGE 3-170)

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

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

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

POTASSIUM CHLORIDE (PAGE 3-171)

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

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

POTASSIUM CITRATE (PAGE 3-173)

>DLT< /TABLET; ORAL/
>ADD< TABLET, CONTROLLED RELEASE; 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

PREDNISOLONE SODIUM PHOSPHATE (PAGE 3-176)

SOLUTION; ORAL
PEDIAPRED
FISONS EQ 5MG BASE/5ML✖ N19157 001 MAY 28, 1986

PREDNISONE (PAGE 3-176)

TABLET; ORAL
DELTASONE
AB UPJOHN 5MG N09986 002
AB 10MG N09986 006
AB 20MG N09986 007

PREDNISONE (PAGE 3-176)

TABLET; ORAL

		PREDNISONE			
> DLT >	/BX/	/BARR LABORATORIES/	/5MG/	/N80701 001/	
> ADD >	AB	BARR LABORATORIES	5MG	N80701 001	
> DLT >	/BX/	/DANBURY PHARMACAL/	/5MG/	/N80356 001/	
> DLT >	/BX/		/10MG/	/N85162 001/	
> DLT >	/BX/		/20MG/	/N85161 001/	
> ADD >	AB	DANBURY PHARMACAL	5MG	N80356 001	
	AB		10MG	N85162 001	
> ADD >	AB		20MG	N85161 001	
> DLT >	/BX/	/DURAMED PHARMS/	/5MG/	/N88394 001/	
	/BX/		/10MG/	/N88395 001/	
	/BX/		/20MG/	/N88396 001/	
> ADD >	AB	DURAMED PHARMS	5MG	N88394 001	OCT 04, 1983
> ADD >	AB		10MG	N88395 001	OCT 04, 1983
> ADD >	AB		20MG	N88396 001	OCT 04, 1983
	AB	MUTUAL PHARM	5MG¤	N89245 001	DEC 04, 1985
	AB		10MG¤	N89246 001	DEC 04, 1985
	AB		20MG¤	N89247 001	DEC 04, 1985
	/BX/	/WEST-WARD/	/50MG/	/N88465 001/	
	AB	WEST-WARD	50MG	N88465 001	JUN 01, 1984
	AB	WEST-WARD	10MG¤	N88832 001	DEC 04, 1985

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

INJECTABLE; INJECTION

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

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

TABLET, CONTROLLED RELEASE; ORAL

	PROCAINAMIDE HCL			
AB	DANBURY PHARMACAL	250MG¤	N89026 001	OCT 22, 1985
AB		500MG¤	N89027 001	OCT 22, 1985
AB		750MG¤	N89042 001	OCT 22, 1985
> ADD > AB	INVAMED	500MG¤	N89284 001	JUN 23, 1986
> ADD >				
	RHYTHMIN			
AB	SIDMAK LABORATORIES	250MG¤	N88958 001	DEC 02, 1985
AB		500MG¤	N88959 001	DEC 02, 1985

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

SYRUP; ORAL

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

TABLET; ORAL

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

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

INJECTABLE; INJECTION

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

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL

INDERAL

>ADD>	AB	AYERST LABS/AMHO	60MG		N16418 009 OCT 18, 1982

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
>ADD> >ADD>	AB	CORD LABORATORIES	10MG¤	N70663 001 JUN 13, 1986
>ADD> >ADD>	AB		20MG¤	N70664 001 JUN 13, 1986
>ADD> >ADD>	AB		40MG¤	N70665 001 JUN 13, 1986
>ADD> >ADD>	AB		80MG¤	N70667 001 JUN 13, 1986

PROPRANOLOL HCL

	AB	DANBURY PHARMACAL	10MG¤	N70175 001 MAY 13, 1986
	AB		20MG¤	N70176 001 MAY 13, 1986
	AB		40MG¤	N70177 001 MAY 13, 1986
	AB		80MG¤	N70178 001 MAY 13, 1986
	AB	DURAMED PHARMS	10MG¤	N70306 001 SEP 09, 1985
	AB		20MG¤	N70307 001 SEP 09, 1985
	AB		40MG¤	N70308 001 SEP 09, 1985
	AB		80MG¤	N70310 001 SEP 09, 1985
>ADD> >ADD>	AB	LEMMON	20MG¤	N70233 001 JUN 23, 1986
>ADD> >ADD>	AB		40MG¤	N70234 001 JUN 23, 1986

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL

PROPRANOLOL HCL

	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> >ADD>	AB	PAR PHARMACEUTICAL	60MG¤	N70220 001 SEP 24, 1986 : JUN 05, 1986
	AB		80MG¤	N70221 001 APR 14, 1986
	AB	WATSON LABS	20MG¤	N70549 001 APR 11, 1986
	AB		40MG¤	N70550 001 APR 11, 1986

PROTAMINE SULFATE (PAGE 3-184)

INJECTABLE; INJECTION

PROTAMINE SULFATE

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

QUAZEPAM (PAGE 3-186)

TABLET; ORAL

DORMALIN

	SCHERING	15MG¤	N18708 001 DEC 27, 1985

QUINIDINE GLUCONATE (PAGE 3-186)

TABLET, CONTROLLED RELEASE; ORAL

QUINALAN

BC	LANNETT	324MG¤	N88081 001 FEB 10, 1986

QUINIDINE GLUCONATE

AB	SUPERPHARM	324MG¤	N89164 001 NOV 21, 1985

RANITIDINE HYDROCHLORIDE (PAGE 3-187)

TABLET; ORAL

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

RIBAVIRIN (PAGE 3-189)

POWDER FOR RECONSTITUTION; INHALATION

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

SECRETIN (PAGE 3-190)

INJECTABLE; INJECTION

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

>ADD> SODIUM BICARBONATE (PAGE 3-191)

>ADD> INJECTABLE; INJECTION

>ADD> SODIUM BICARBONATE IN PLASTIC CONTAINER

>ADD>	ABBOTT LABORATORIES	0.9MEQ/ML*	N19443 001 JUN 03, 1986
>ADD>		1MEQ/ML*	N19443 002 JUN 03, 1986

SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-191)

GRANULE, EFFERVESCENT; ORAL

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

SODIUM CHLORIDE (PAGE 3-191)

INJECTABLE; INJECTION

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

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

CAPSULE; ORAL

	SODIUM IODIDE I-123		
	◑ BENEDICT NUCLR PHARM	400 UCI	N18671 003 MAY 27, 1982

SODIUM NITROPRUSSIDE (PAGE 3-194)

INJECTABLE; INJECTION

	NITROPRESS		
>ADD> AP >ADD>	ABBOTT LABORATORIES	50MG/VIAL*	N70566 001 JUN 09, 1986

SOMATREM (PAGE 3-195)

INJECTABLE; INJECTION

	PROTROPIN		
	GENENTECH	5MG/VIAL*	N19107 001 OCT 17, 1985

SOMATROPIN (PAGE 3-195)

INJECTABLE; INJECTION

	ASELLACRIN 10		
	◑ SERONO LABS	10 IU/VIAL	N17726 001
	ASELLACRIN 2		
	◑ SERONO LABS	2 IU/VIAL	N17726 002 JUL 21, 1983
	CRESCORMON		
	◑ KABIVITRUM	4 IU/VIAL	N17992 001

SULCONAZOLE NITRATE (PAGE 3-197)

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

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

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

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

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
/SULFUR COLLOID KIT/
/AP/ /SYNCOR INTL/ /N/A/ /N17858 001/
AN-SULFUR COLLOID
AP CIS-US N/A N17858 001
/TECHNECOLL/
/AP/ /MALLINCKRODT/ /N/A/ /N17059 001/
/TESULOID/
/AP/ /ER SQUIBB AND SONS/ /N/A/ /N16923 001/

SOLUTION; INJECTION, ORAL
TECHNECOLL
AP MALLINCKRODT N/A N17059 001
TESULOID
AP ER SQUIBB AND SONS N/A N16923 001

TEMAZEPAM (PAGE 3-203)

CAPSULE; ORAL

	RESTORIL			
AB	SANDOZ PHARMS/SANDOZ	15MG	N18163 001	
AB		30MG	N18163 002	
	/SOMAZ/			
	TEMAZ			
AB	QUANTUM PHARMICS	15MG¤	N70564 001 OCT 15, 1985	> ADD >
AB		30MG¤	N70547 001 OCT 15, 1985	> ADD >

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	
> ADD >	THEOPHYLLINE-SR			
> ADD > BC	RP SCHERER	300MG¤	N88255 001 JUN 12, 1986	
> ADD >				

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

THEOPHYLLINE (PAGE 3-206)

TABLET, CHEWABLE; ORAL

	THEOPHYL		
	MCNEIL PHARM	100MG¤	N86506 001 SEP 12, 1985

TABLET, CONTROLLED RELEASE; ORAL

	THEO-DUR			
	KEY PHARMACEUTICALS	450MG¤	N89131 001 JUN 25, 1986	> ADD >

THIORIDAZINE HYDROCHLORIDE (PAGE 3-209)

CONCENTRATE; ORAL

	THIORIDAZINE HCL INTENSOL		
AA	ROXANE LABORATORIES	30MG/ML¤	N88941 001 DEC 16, 1985
AA		100MG/ML¤	N88942 001 DEC 16, 1985

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL

	TOLAZAMIDE		
AB	BARR LABORATORIES	100MG¤	N70162 001 JAN 14, 1986
AB		250MG¤	N70163 001 JAN 14, 1986
AB		500MG¤	N70164 001 JAN 14, 1986
AB	CHELSEA LABORATORIES	100MG¤	N70285 001 JAN 09, 1986
AB		250MG¤	N70286 001 JAN 09, 1986
AB		500MG¤	N70287 001 JAN 09, 1986
AB	COLMED LABORATORIES	250MG¤	N70168 001 APR 02, 1986
AB		500MG¤	N70169 001 APR 02, 1986
AB	CORD LABORATORIES	250MG¤	N70289 001 MAR 13, 1986
AB		500MG¤	N70290 001 MAR 13, 1986
AB	DANBURY PHARMACAL	100MG¤	N70513 001 JAN 09, 1986
AB		250MG¤	N70514 001 JAN 09, 1986
AB		500MG¤	N70515 001 JAN 09, 1986

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL
TOLAZAMIDE

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
> ADD > AB	SUPERPHARM	250MG*		N70763 001 JUN 16, 1986
> ADD > AB		500MG*		N70764 001 JUN 16, 1986

TRIENTINE HYDROCHLORIDE (PAGE 3-216)

CAPSULE; ORAL
CUPRID

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

TRIMETHOBENZAMIDE HYDROCHLORIDE (PAGE 3-217)

INJECTABLE; INJECTION
TRIMETHOBENZAMIDE HCL

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

TRIMETHOPRIM (PAGE 3-218)

TABLET; ORAL
TRIMETHOPRIM

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

TROPICAMIDE (PAGE 3-219)

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE

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

VALPROIC ACID (PAGE 3-220)

CAPSULE; ORAL
DEPAKENE

AB	ABBOTT LABORATORIES	250MG		N18081 001

VALPROIC ACID

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

VANCOMYCIN HYDROCHLORIDE (PAGE 3-220)

CAPSULE; ORAL
VANCOCIN HCL

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

INJECTABLE; INJECTION
VANCOCIN HCL

	ELI LILLY	EQ 1GM BASE/VIAL*		N62476 002 MAR 21, 1986
		EQ 1GM BASE/VIAL*		N60180 002 MAR 21, 1986

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION
VERAPAMIL HCL

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

VINBLASTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION

VELBAN

/ELI LILLY/ /1MG/AMP/ /N12665.001/

AP	ELI LILLY	10MG/VIAL	N12665 001

VINBLASTINE SULFATE

AP	LYPHOMED	10MG/VIAL*	N89011 001 NOV 18, 1985

VINCRISTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION

ONOCOVIN

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

VINCRISTINE SULFATE

AP	QUAD PHARMS	1MG/ML*	N70777 001 APR 29, 1986
AP		1MG/ML*	N70778 001 MAY 01, 1986

WARFARIN SODIUM (PAGE 3-221)

TABLET; ORAL

COUMADIN

/BX/ /DUPONT PHARMS/DUPONT/2.5MG/ /N09218.018/

AB	DUPONT PHARMS/DUPONT	2.5MG	N09218 018

WARFARIN SODIUM

AB	COLMED LABORATORIES	2.5MG*	N88720 001 AUG 06, 1985

> ADD > ZINC CHLORIDE (PAGE 3-223)

> ADD > INJECTABLE; INJECTION
> ADD > ZINC CHLORIDE IN PLASTIC CONTAINER

> ADD >	ABBOTT LABORATORIES	EQ 1MG ZINC/ML*	N19559 001 JUN 26, 1986

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; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-225)

> ADD >
> ADD >
> ADD >
TABLET, CONTROLLED RELEASED; ORAL
PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE
DORSEY LABS/SANDOZ — 12MG;75MG* — N19613 001 — JUN 16, 1986

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-225)

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

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX (PAGE 3-225)

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

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-225)

SYRUP; ORAL
> ADD >
> ADD >
> ADD >
BELDIN
HALSEY DRUG — 12.5MG/5ML* — N89179 001 — JUN 05, 1986
DIPHEN
BAY LABORATORIES — 12.5MG/5ML* — N70118 001 — OCT 01, 1985
HYDRAMINE
NATL PHARM MFG/BARRE — 12.5MG/5ML* — N70205 001 — JAN 28, 1986

DOXYLAMINE SUCCINATE (PAGE 3-225)

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

IBUPROFEN (PAGE 3-225)

TABLET; ORAL
IBUPROFEN
BARR LABORATORIES — 200MG* — N70493 001 — SEP 24, 1986 : DEC 24, 1985
CHELSEA LABORATORIES — 200MG* — N70605 001 — SEP 24, 1986 : MAY 07, 1986
DANBURY PHARMACAL — 200MG* — N70435 001 — SEP 24, 1986 : MAR 05, 1986
PAR PHARMACEUTICAL — 200MG* — N70481 001 — SEP 24, 1986 : OCT 18, 1985
MEDIPREN
MCNEIL CONSUMER PROD — 200MG* — N70475 001 — SEP 24, 1986 : FEB 06, 1986
> ADD > — 200MG* — N71215 001 — SEP 24, 1986 : JUN 26, 1986
> ADD >

INSULIN SUSPENSION, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION
HUMULIN BR
ELI LILLY — 100 UNITS/ML* — N19529 001 — APR 28, 1986

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

INJECTABLE; INJECTION
HUMULIN N
ELI LILLY — 100 UNITS/ML — N18781 001 — OCT 28, 1985

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

INJECTABLE; INJECTION
INSULATARD NPH HUMAN
NORDISK USA — 100 UNITS/ML* — N19449 001 — MAY 30, 1986

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

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

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

INJECTABLE; INJECTION
VELOSULIN HUMAN
NORDISK USA — 100 UNITS/ML¤ — N19450 001 MAY 30, 1986

OXYMETAZOLINE HYDROCHLORIDE (PAGE 3-228)

SOLUTION/DROPS; OPHTHALMIC
OCUCLEAR
SCHERING — 0.025%¤ — N18471 001 MAY 30, 1986

POVIDONE-IODINE (PAGE 3-228)

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

PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-228)

CAPSULE; CONTROLLED RELEASE; ORAL
/SUDAFED S.A./
SUDAFED 12 HOUR

PYRITHIONE ZINC (PAGE 3-228)

LOTION; TOPICAL
HEAD & SHOULDERS CONDITIONER
PROCTER AND GAMBLE — 0.3%¤ — N19412 001 MAR 10, 1986
0.3%¤ — N19412 002 MAR 10, 1986
0.3%¤ — N19412 003 MAR 10, 1986
0.3%¤ — N19412 004 MAR 10, 1986

NO SEPTEMBER - JUNE APPROVALS

C. APPENDICES

1. Orphan Drug Products with Exclusive Approval

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

3. Biopharmaceutic Guidance Availability List

4. ANDA Suitability Petitions

5. Exclusivity Terms

6. Prescription and OTC Drug Product Patent and Exclusivity Data

APPENDIX 1

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

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

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

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

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

APPENDIX 1

BIOLOGICAL PRODUCTS

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

APPENDIX 1

DRUG PRODUCTS

Active Ingred.(s) Strength(s)	Trade Name Dosage Form; Route	Applicant	Appl. Prod. Approval Date	Exclusivity Exp. Date
Chenodiol 250mg	Chenix Tablet; Oral	Rowell Laboratories	18513 002 Jul 28, 1983	ODE Jul 28, 1990
Cromolyn Sodium 4%	Opticrom Solution/Drops; Ophthalmic	Fisons	18155 001 Oct 3, 1984	ODE Oct 3, 1991
Carnitine, L- 330mg	L-Carnitine Tablet; Oral	Sigma-Tau	18948 001 Dec 27, 1985	ODE Dec 27, 1992
Carnitine, L- 1gm/10ml	Vitacarn Solution; Oral	Kendall McGaw Labs*	19257 001 Apr 10, 1986	
Naltrexone Hydrochloride 50mg	Trexan Tablet; Oral	Dupont Pharms	18932 001 Nov 20, 1984	ODE Nov 20, 1991
Monooctanoin 100%	Moctanin Liquid; Perfusion Biliary	Ascot Hosp Pharms	19368 001 Oct 29, 1985	ODE Oct 29, 1992
Pentamidine Isethionate 300mg/ml	Pentam 300 Injectable; Injection	LyphoMed	19264 001 Oct 16, 1984	ODE Oct 16, 1991

(continued)

*Refer to Appendix I narrative

APPENDIX 1

DRUG PRODUCTS

(continued)

Active Ingred.(s) Strength(s)	Trade Name Dosage Form; Route	Applicant	Appl. Prod. Approval Date	Exclusivity Exp. Date
Potassium Citrate 5meq	Urocit-K Tablet; Oral	Univ of Tx Hlth Sci Ctr	19071 001 Aug 30, 1985	ODE Aug 30, 1992
Somatrem 5mg/vial	Protropin Injectable; Injection	Genentech	19107 001 Oct 17, 1985	ODE Oct 17, 1992
Trientine Hydrochloride 250mg	Cuprid Capsule; Oral	Merck Sharp and Dohme Res Labs	19194 001 Nov 8, 1985	ODE Nov 08, 1992

APPENDIX 2

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

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

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

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

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

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

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

Aminophylline
Tablet; Oral
100mg
200mg

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

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

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

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

Aspirin; Carisoprodol
Tablet; Oral
325mg; 200mg

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

Aspirin; Meprobamate
Tablet; Oral
325mg; 200mg

Aspirin; Methocarbamol
Tablet; Oral
325mg; 200mg

Chlorothiazide
Tablet; Oral
250mg

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

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

APPENDIX 3

BIOPHARMACEUTIC GUIDANCE AVAILABILITY LIST

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

Name of Drug	Date	Revised Date
Acetohexamide	Nov 15, 1985	
Allopurinol	Jul 15, 1985	
Amiloride Hydrochloride	Mar 29, 1985	
Aminophylline Suppositories	Jul 05, 1983	
Amitriptyline Hydrochloride	Jul 05, 1983	
Anticholinergic Drugs (Controlled Release)	Nov 07, 1980	
Baclofen	May 05, 1986	
Carbamazepine	Dec 05, 1984	
Chlordiazepoxide Hydrochloride	Jul 05, 1983	
Chlorpropamide	Jul 05, 1983	
Chlorthalidone	Jul 05, 1983	
Clofibrate	Apr 07, 1986	
Clonidine Hydrochloride	Dec 05, 1984	
Clorazepate Dipotassium	Mar 10, 1986	
Diazepam (revised)	Jul 08, 1985	
Dicyclomine Hydrochloride	Aug 10, 1984	
Dipyridamole	Jul 05, 1983	
Disopyramide Phosphate	Jul 09, 1985	

(continued)

APPENDIX 3

(continued)

Name of Drug	Date	Revised Date
Dissolution Testing (General)	Apr 19, 1985	
Doxepin Hydrochloride	Apr 02, 1985	
Erythromycin	Apr 05, 1977	
Flurazepam	Oct 15, 1985	
Hydrochlorothiazide	Jul 25, 1983	
Hydroxyzine Hydrochloride (Dissolution Only)	Jan 27, 1981	
Hydroxyzine Pamoate	Jul 26, 1983	
Indomethacin	Apr 06, 1985	
Isosorbide Dinitrate	Jun 04, 1985	
Isosorbide Dinitrate (Controlled Release Products)	Sep 19, 1985	
Lorazepam	Dec 03, 1984	
*Methylprednisolone	Jun 12, 1986	
Methyltestosterone	Nov 16, 1979	
Metoclopramide	Dec 27, 1984	
Minoxidil	Apr 02, 1986	
Nitrofurantoin (Macrocrystalline)	Oct 29, 1985	
Phentermine Hydrochloride (Dissolution)	Nov 21, 1980	
Phentermine Hydrochloride (Slow Dissolving; Dissolution)	Nov 21, 1980	
Phenylbutazone & Oxyphenbutazone	Jul 26, 1983	
Prednisone (Dissolution Only)	Jul 10, 1985	
Probenecid	Jul 26, 1983	
Procainamide	Jul 25, 1983	
Propranolol	May 19, 1984	
Quinidine Gluconate (Controlled Release)	Jun 15, 1981	
Spironolactone	Jul 25, 1983	
Sulfinpyrazone	Jul 15, 1983	
Temazepam	Aug 1985	
Theophylline (Controlled Release)	Apr 1984	
Theophylline (Immediate Release)	Nov 02, 1983	
Tolazamide	Aug 22, 1984	
Tolbutamide	Jan 1982	
Trazodone	Nov 15, 1985	Apr 30, 1986
Verapamil	Jul 1985	

*New Addition

*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 (Container Size)	Docket Number	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Elixir; Oral	160mg/5ml 6mg/5ml	86 P-0133/CP	New Strength	Approved May 21, 1986
Acetaminophen; Codeine Phosphate Capsule; Oral	500mg 30mg	84 P-0228/CP	New Dosage Form New Strength	Approved Jun 02, 1986
Acetaminophen; Codeine Phosphate Capsule; Oral	500mg 60mg	84 P-0228/CP	New Dosage Form New Strength	Approved Jun 02, 1986
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	300mg 30mg	85 P-0543/CP	New Dosage Form	Approved Mar 18, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Acetaminophen; 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
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 15mg	86 P-0161/CP	New Strength	Approved May 8, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 30mg	86 P-0161/CP	New Strength	Approved May 8, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 60mg	86 P-0161/CP	New Strength	Approved May 8, 1986
Acetaminophen; Hydrocodone Bitartrate Solution; Oral	500mg/15ml 5mg/15ml	84 P-0391/CP	New Dosage Form	Approved Jul 2, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
5-Aminosalicylic Acid Suppository; Rectal	500mg	84 P-0425/CP	New Ingredient	Approved Jun 05, 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
Bretylium Tosylate Injectable; Injection	100mg/ml	86 P-0157/CP	New Strength	Approved May 8, 1986
Brompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	12mg 120mg	85 P-0095/CP	New Combination New Dosage Form	Approved Dec 13, 1985
Chlorpheniramine Maleate; Phenylpropanolamine Hydrochloride Controlled-release Capsule; Oral	10mg 75mg	85 P-0149/CP	New Strength	Approved Dec 13, 1985

(continued)

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Chlorhexidine Gluconate Solution; Topical	1.5%	84 P-0417/CP	New Strength	Approved Sep 18, 1985
Cholestyramine Tablet, Chewable; Oral	Eq 4gm Resin	86 P-0123/CP Form	New Dosage Jun 20, 1986	Approved
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
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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Dexbrompheniramine Maleate; Pseudoephedrine Sulfate Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/ CP0002	New Dosage Form	Approved Jan 22, 1986
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
Disopyramide Phosphate Tablet, Controlled Release; Oral	200mg 300mg	84 N-0116/CP	New Dosage Form New Strength	Approved Jun 03, 1986
Disulfiram Suspension; Oral	500mg/30ml	85 P-0215/CP	New Dosage Form	Approved Oct 8, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Estradiol Tablet; Oral	0.5mg	84 P-0308/CP	New Strength	Approved Mar 24, 1986
Fluorouracil Injectable; Injection	25mg/ml	85 P-0208/CP	New Strength	Approved Oct 8, 1985
Fluorouracil Injectable; Injection	50mg/20ml	86 P-0080/CP	New Strength	Approved Apr 2, 1986
Flurazepam Concentrate; Oral	30mg/ml	85 P-0081/CP	New Dosage Form	Approved Jul 10, 1985
Flurazepam Hydrochloride Solution; Oral	15mg/5ml	85 P-0091/CP	New Dosage Form	Approved Oct 25, 1985
Furosemide Solution; Oral	40mg/5ml	85 P-0106/ CP0002	New Strength	Approved Sep 19, 1985
Furosemide Concentrate; Oral	80mg/ml	85 P-0106/CP	New Strength	Approved Sep 19, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
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
Isoniazid Concentrate; Oral	50mg/ml	85 P-0468/CP	New Strength	Approved Dec 13, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
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
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 20ml/vial	86 P-0036/CP	New Strength	Approved Mar 18, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
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
Naloxone Hydrochloride Injectable; Injection	1mg/ml 5ml/vial	86 P-0079/CP	New Strength	Approved May 7, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Naloxone Hydrochloride Injectable; Injection	1mg/ml 10ml/vial	86 P-0079/CP	New Strength	Approved May 7, 1986
Nitroglycerin Injectable; Injection	5mg/ml	86 P-0025/CP	New Strength	Approved Apr 1, 1986
Nitroglycerin Injectable; Injection	10mg/ml	85 P-0134/CP	New Strength	Approved Sep 19, 1985
Nitroglycerin in 5% Dextrose Injectable; Injection	10mg/100ml (500ml Container)	86 P-0099/CP	New Strength	Approved Apr 1, 1986
Nitroglycerin in 5% Dextrose Injectable; Injection	20mg/100ml (250ml Container)	86 P-0099/ CP0002	New Strength	Approved Apr 1, 1986
Nitroglycerin in 5% Dextrose Injectable; Injection	40mg/100ml (250ml and 500ml Containers)	86 P-0099/ CP0003	New Strength	Approved Apr 1, 1986
Probucol Tablet; Oral	500mg	85 P-0337/CP	New Strength	Approved Oct 25, 1985
Procainamide Hydrochloride Tablet; Oral	375mg	85 P-0125/CP	New Strength	Approved Sep 19, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
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
Propranolol Hydrochloride Tablet, Controlled Release; Oral	80mg 120mg 160mg	85 P-0197/CP	New Dosage Form	Approved Sep 27, 1985

(continued)

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Pyridostigmine Bromide Tablet; Oral	30mg	85 P-0412/CP	New Strength	Approved Jan 22, 1986
Ritodrine Hydrochloride in Dextrose 5% Injectable; Injection	30mg/100ml (500ml Container)	86 P-0100/CP	New Strength	Approved May 7, 1986
Scopolamine Transdermal System/24 Hour Film, Controlled Release; Percutaneous	1mg	85 P-0168/CP	New Strength (Dosing Interval)	Approved Sep 27, 1985
Spironolactone Syrup; Oral	25mg/5ml	85 P-0510/CP	New Dosage Form	Approved Jan 22, 1986
Spironolactone Oral; Injection	25mg/5ml	86 P-0055/CP	New Dosage Form	Approved Mar 28, 1986
Theophylline Capsule; Oral	150mg 300mg	85 P-0175/CP	New Strength	Approved Oct 8, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Thiothixene Hydrochloride Solution; Oral	5mg/5ml	86 P-0178/CP	New Strength	Approved Jun 04, 1986
Vinblastine Sulfate Injectable; Injection	1mg/ml	86 P-0056/CP	New Dosage Form	Approved Mar 28, 1986
Vincristine Sulfate Injectable; Injection	2mg/vial	85 P-0016/CP	New Dosage Form	Approved Nov 8, 1985

APPENDIX 4

II. Petitions Denied

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	650mg 10mg	85 P-0015/CP	New Strength	Denied Nov 7, 1985
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	750mg 7.5mg	85 P-0169/CP	New Strength	Denied Nov 7, 1985
Acetaminophen Methocarbamol Tablet; Oral	325mg 400mg	85 P-0102/CP	New Combination	Denied Jun 24, 1986
Aminocaproic Acid Injectable; Injection	500mg/ml	85 P-0064/CP	New Strength	Denied May 29, 1985
Aminophylline Injectable; Injection	10mg/ml	85 P-0066/CP	New Strength	Denied May 3, 1985
Aminophylline Injectable; Injection	50mg/ml	85 P-0066/CP	New Strength	Denied May 3, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Reason for Petition	Status
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml 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
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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

APPENDIX 5

EXCLUSIVITY TERMS

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

ABBREVIATIONS

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

REFERENCES

NEW DOSING SCHEDULE

D-1	ONCE A DAY APPLICATION
D-2	ONCE DAILY DOSING
D-3	SEVEN DAYS/SEVEN DAYS/SEVEN DAYS DOSING SCHEDULE
D-4	SEVEN DAYS/FOURTEEN DAYS DOSING SCHEDULE
D-5	TEN DAYS/ELEVEN DAYS DOSING SCHEDULE
D-6	SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE
D-7	BID DOSING

(continued)

APPENDIX 5

(continued)

NEW DOSING SCHEDULE

D-8	INTRAVENOUS, EPIDURAL AND INTRATHECAL DOSING
D-9	NARCOTIC OVERDOSE IN ADULTS
D-10	NARCOTIC OVERDOSE IN CHILDREN
D-11	POSTOPERATIVE NARCOTIC DEPRESSION IN CHILDREN
D-12	BEDTIME DOSING OF 800MG FOR TREATMENT

NEW INDICATION

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

(continued)

APPENDIX 5

(continued)

NEW INDICATION

I-17	PITUITARY TUMORS
I-18	POSTMENOPAUSAL OSTEOPOROSIS
I-19	ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
I-20	CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE
I-21	ACUTE/OTITIS/MEDIA
I-22	EXERCISE INDUCED BRONCHOSPASMS
I-23	MYOCARDIAL INFARCTION OR STROKE
I-24	COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL
I-25	BLASTOMYCOSES DERMATITIDES
I-26	PEDIATRIC SUBARACHNOID VASCULAR
I-27	PETRIELLIDIUM BOYDII INFECTION
I-28	HEREDITARY ANGIOEDEMA
I-29	INTRACORONARY USE
I-30	PEDIATRIC USE
I-31	DIRECT ISOTOPIC CYSTOGRAPHY
I-32	POSTPARTUM HEMORRHAGE
I-33	USE IN METHODONE INDUCED RESPIRATORY DEPRESSION
I-34	PROLACTIN SECRETING ADENOMAS
I-35	ANGINA PECTORIS DUE TO CORONARY ATHEROSCLEROSIS
I-36	ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
I-37	SPINAL ANESTHESIA
I-38	PATIENT PREOPERATIVE SKIN PREPARATION
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
I-42	MAINTENANCE THERAPY AT REDUCED DOSE FOLLOWING HEALING OF ACUTE DUODENAL ULCER
I-43	TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE
ADD I-44	TREATMENT OF SEVERE RECALCITRANT DERMATOPHYTE INFECTIONS

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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 - JUNE ACTIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
/12142/001/	/4537883/	/AUG/27,/2002/		
/12142/002/	/4537883/	/AUG/27,/2002/		
/12142/003/	/4537883/	/AUG/27,/2002/		
/12142/004/	/4537883/	/AUG/27,/2002/		
/12142/005/	/4537883/	/AUG/27,/2002/		
12142 006	4537883	AUG 27, 2002		
12142 007	4537883	AUG 27, 2002		
12142 008	4537883	AUG 27, 2002		
12142 009	4537883	AUG 27, 2002		
12142 010	4537883	AUG 27, 2002		
12365 005	4534973	AUG 13, 2002		
12366 002	4534974	AUG 13, 2002		
13601 001			I-40	JAN 31, 1988
13601 002			I-40	JAN 31, 1988
/14715/001/	/3428735/	/FEB/18,/1986/		
14715 004	3428735	FEB 18, 1986		
/16273/001/	/4324779/	/APR/13,/1999/		
/16273/002/	/4324779/	/APR/13,/1999/		
/16273/003/	/4324779/	/APR/13,/1999/		
/16363/001/	/4324779/	/APR/13,/1999/		
16636 002			D-9	SEP 24, 1986
			D-10	
			D-11	
			I-33	
16983 001			I-36	SEP 09, 1988
16990 001	3634582	JAN 11, 1989		
	3860618	JAN 14, 1992		
17560 001	RE28636	JUN 02, 1987	/I-21/	/SEP/24,/1986/
17560 002	RE28636	JUN 02, 1987	/I-21/	/SEP/24,/1986/
17581 001	3998966	DEC 21, 1993	/NS/	/SEP/24,/1986/
17601 001	/3419565/	/DEC/31,/1985/		
	/3717641/	/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

(continued)

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APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
17768 001	3855140	DEC 17, 1991	I-38	SEP 24, 1986
	3960745	DEC 17, 1991		
17785 001			NDF	MAR 07, 1989
17862 001	4536386	AUG 20, 2002	I-12	SEP 24, 1986
			I-13	SEP 24, 1986
			I-14	SEP 24, 1986
17862 002	4536386	AUG 20, 2002	I-12	SEP 24, 1986
			I-13	SEP 24, 1986
			I-14	SEP 24, 1986
17862 003	4536386	AUG 20, 2002	I-12	SEP 24, 1986
			I-13	SEP 24, 1986
			I-14	SEP 24, 1986
17920 005	3950373	APR 13, 1993	D-12	APR 30, 1989
	4024271	MAY 17, 1994		
17970 001	4536516	AUG 20, 2002	I-39	DEC 10, 1988
18044 001			I-41	JAN 22, 1989
18044 002			I-41	JAN 22, 1989
18052 001	/3839573/	/OCT/01,/1991/		
18053 003			I-37	SEP 25, 1988
18147 002	/RE29668/	/DEC/10,/1991/		
	/4100347/	/JUL/11,/1995/		
	/3927002/	/DEC/16,/1992/		
18147 003	/RE29668/	/DEC/10,/1991/		
	/4100347/	/JUL/11,/1995/		
	/3927002/	/DEC/16,/1992/		
/18154/001/	/3461461/	/AUG/12,/1986/		
18154 001	3461461	MAY 07, 1985		
/18154/003/	/3461461/	/AUG/12,/1986/		
18154 003	3461461	MAY 07, 1985		
18155 001			ODE	OCT 03, 1991
18181 001	/3839573/	/OCT/01,/1991/		
18182 001	/3839573/	/OCT/01,/1991/		
18183 001	/3839573/	/OCT/01,/1991/		
18217 001	4035376	JUL 12, 1994	NCE	DEC 24, 1990
18230 001	/3839573/	/OCT/01,/1991/		

> ADD >

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
18240 001			I-35	SEP 04, 1988
18240 002			I-35	SEP 04, 1988
/18257/001/	/4237068/	/DEC/02,/1997/		
18257 001	4237068	NOV 09, 1998		
18257 002	/4237068/	/DEC/02,/1997/		
18257 002	4237068	NOV 09, 1998		
18401 001	3433791	MAR 18, 1986		
18423 001	3855140	DEC 17, 1991		
	3960745	DEC 17, 1991		
18471 001			NDF	MAY 30, 1989
18482 001	3784684	JAN 08, 1991		
18506 001	/3419565/	/DEC/31,/1985/		
	/3717647/	/FEB/20,/1996/		
18509 001			NP	AUG 07, 1988
18513 002			ODE	JUL 28, 1990
18533 001			I-44	JUN 30, 1989
18587 003	3658993	APR 25, 1989	NCE	SEP 07, 1992
18644 001	3819706	JUN 25, 1991	NCE	DEC 30, 1990
	3885046	MAY 20, 1992		
	4057323	MAR 26, 2002		
	4347257	AUG 31, 1999		
	4393078	JUL 12, 2000		
	4425363	JAN 10, 2001		
	4435449	MAR 06, 2001		
	4438138	MAR 20, 2001		
18644 002	3819706	JUN 25, 1991	NCE	DEC 30, 1990
	3885046	MAY 20, 1992		
	4057323	MAR 26, 2002		
	4347257	AUG 31, 1999		
	4393078	JUL 12, 2000		
	4425363	JAN 10, 2001		
	4435449	MAR 06, 2001		
	4438138	MAR 20, 2001		

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	18644 003	3819706	JUN 25, 1991	NCE	DEC 30, 1990
		3885046	MAY 20, 1992		
		4057323	MAR 26, 2002		
		4347257	AUG 31, 1999		
		4393078	JUL 12, 2000		
		4425363	JAN 10, 2001		
		4435449	MAR 06, 2001		
		4438138	MAR 20, 2001		
	18654 001	4280957	JUL 28, 1998	NCE	DEC 20, 1990
	18677 001	4087545	MAY 02, 1995	NCE	DEC 26, 1990
		4087547	MAY 02, 1995		
>_DLT_>	/18682/001/	/4062966/	/DEC/13,/1993/	/NCE/	/SEP/24,/1986/
>_ADD_>	18682 001	4062966	DEC 13, 1994	NCE	FEB 18, 1993
	18683 001	4393871	JUL 19, 2000		
>_DLT_>	/18689/001/	/3708579/	/JAN/02,/1992/		
>_ADD_>	18689 001	3708579	JAN 02, 1992		
	18701 001	3438991	APR 15, 1986	NE	JAN 14, 1989
	18703 001			I-42	MAY 30, 1989
	18703 001			I-43	MAY 30, 1989
	18703 002	4128658	DEC 05, 1995	NCE	JUN 09, 1993
		4521431	JUN 04, 2002	I-15	JUN 28, 1988
				I-42	MAY 30, 1989
				I-43	MAY 30, 1989
	18705 001			NDF	OCT 31, 1988
	18708 001	3845039	OCT 29, 1991	NCE	DEC 27, 1990
		3920818	NOV 18, 1992		
	18713 001	/3839573/	/OCT/01,/1991/		
	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
>_DLT_>	/18770/001/	/4138581/	/FEB/06,/1996/	/NCE/	/DEC/28,/1989/
>_ADD_>	18770 001	4138581	FEB 06, 1998	NCE	DEC 28, 1989
	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		
>_DLT_>	/18917/001/	/3857952/	/DEC/31,/1991/		
>_ADD_>	18917 001	3857952	DEC 31, 1993		
>_DLT_>	/18917/003/	/3857952/	/DEC/31,/1991/		
>_ADD_>	18917 003	3857952	DEC 31, 1993		
	18928 001	4221778	SEP 09, 1997		
	18932 001			ODE	NOV 20, 1991
	18948 001			NCE	DEC 27, 1990
				ODE	DEC 27, 1992
>_DLT_>	/18949/001/	/3878217/	/APR/15,/1992/	/NCE	/MAY/08,/1990/
>_ADD_>	18949 001	3878217	APR 15, 1994	NCE	MAY 08, 1990
		/3886526/	/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, 19980		
	18956 002	4021481	MAY 03, 1994	NCE	DEC 26, 1990
		4250113	FEB 10, 1998		

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APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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	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 >ADD>
			ODE	NOV 11, 1992
19215 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990
19219 002	3641152	FEB 08, 1989	NCE	DEC 19, 1990
19257 001			NDF	APR 10, 1989
			ODE*	DEC 27, 1992
19259 001	3980778	SEP 14, 1993		
19260 001	3980778	SEP 14, 1993		
19264 001			ODE	OCT 16, 1991
19270 001	4252984	FEB 24, 1998	NCE	AUG 30, 1990
	4311708	JAN 19, 1999		
	4342783	AUG 03, 1999		
19322 001	3721687	MAR 20, 1990	NCE	DEC 27, 1990
19323 001	3721687	MAR 20, 1990	NCE	DEC 27, 1990
19359 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990
19368 001	4205086	MAY 27, 1997	NCE	OCT 29, 1990
			ODE	OCT 29, 1992
19412 001			NS	MAR 10, 1989
19412 002			NS	MAR 10, 1989
19412 003			NS	MAR 10, 1989
19412 004			NS	MAR 10, 1989
19425 001	4012444	MAR 15, 1994	NCE	AUG 01, 1994
	4066755	JAN 03, 1995		
19434 001	3950333	APR 13, 1993		
	4024271	MAY 17, 1994		
19435 001	4024163	MAY 17, 1994	NCE	MAR 31, 1991
19439 001			NS	JUN 13, 1989
19478 001	3644627	FEB 22, 1989		
	3784684	JAN 08, 1991		

*REFER TO APPENDIX I NARRATIVE

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