CUMULATIVE SUPPLEMENT 5 AUG'85-JAN'86

"APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

6TH EDITION

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

A. INTRODUCTION

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APPROVED DRUG PRODUCTS

with

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CUMULATIVE SUPPLEMENT

JANUARY 1986

A. INTRODUCTION

1. HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

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

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

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

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

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

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

2. APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

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

(continued)

APPLICANT (NAME) CHANGES

(continued)

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

3. PREDNISONE BIOEQUIVALENCE

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

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

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

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

4. OTC DRUG PRODUCTS

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

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

5. THEO-DUR 200MG AND 300MG TABLETS

Key Pharmaceuticals has submitted an acceptable "food effect study" which demonstrated that food does not alter the rate and extent of absorption of theophylline from their Theo-Dur controlled release dosage form. Therefore, labeling for Theo-Dur 200mg and 300mg controlled-release tablets will indicate these findings.

6. 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)
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)

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
DRUG PRODUCTS LISTED	8048	8230
SINGLE SOURCE	2096 (26.0%)	2100 (25.5%)
MULTISOURCE(1)	5952 (74.0%)	6130 (74.5%)
THERAPEUTICALLY EQUIVALENT	4864 (60.5%)	5034 (61.2%)
NOT THERAPEUTICALLY EQUIVALENT	1054 (13.1%)	1058 (12.9%)
EXCEPTIONS(2)	34 (0.4%)	38 (0.4%)
NEW MOLECULAR ENTITIES APPROVED	-	3
NUMBER OF APPLICANTS	306	313

B. ACTIVITY FOR SUPPLEMENT NUMBER 5

	NOV '85	DEC '85	JAN '86	CUMULATIVE
DRUG PRODUCTS ADDED:	57	85	81	223
NEWLY APPROVED	50	84	81	215
DESI EFFECTIVE	5	1	0	6
REMARKETED	2	0	0	2
DRUG PRODUCTS REMOVED:	0	0	0	0
WITHDRAWN APPROVAL	0	0	0	0
RX TO OTC SWITCH	0	0	0	0
NET GAIN IN DRUG PRODUCTS	57	85	81	223
SINGLE SOURCE PRODUCTS APPROVED	6	36	8	50
MULTISOURCE DRUG PRODUCTS APPROVED	51	49	73	173
NEW MOLECULAR ENTITIES APPROVED:	3	16	2	21
AS THE ENTITY	0	7	1	8
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	3	9	1	13

(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; BUTALBITAL (PAGE 3-1)

CAPSULE; ORAL

> ADD > BANCAP

> ADD > FOREST PHARM/FOREST 325MG;50MG¤ N88889 001

> ADD > JAN 16, 1986

TABLET; ORAL

SEDAPAP-10

MAYRAND 650MG;50MG¤ N88944 001

OCT 17, 1985

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL

> ADD > MEDIGESIC PLUS

> ADD > AB US CHEM MKTG GROUP 325MG;50MG;40MG¤ N89115 001

> ADD > JAN 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 #2

AA SUPERPHARM 300MG;15MG¤ N89183 001

OCT 18, 1985

ACETAMINOPHEN AND CODEINE PHOSPHATE #3

AA SUPERPHARM 300MG;30MG¤ N89184 001

OCT 18, 1985

ACETAMINOPHEN AND CODEINE PHOSPHATE #4

AA SUPERPHARM 300MG;60MG¤ N89185 001

OCT 18, 1985

ACETAMINOPHEN W/ CODEINE

/AA/ /VITARINE/ /300MG;30MG/ /N85917.001/

ACETAMINOPHEN W/ CODEINE #2

/AA/ /VITARINE/ /300MG;15MG/ /N87433.001/

ACETAMINOPHEN W/ CODEINE #4

/AA/ /VITARINE /300MG;60MG/ /N87423.001/

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

AA DM GRAHAM LABS 500MG;5MG¤ N89006 001

AUG 09, 1985

BANCAP HC

AA FOREST PHARM/FOREST 500MG;5MG N87961 001

MAR 17, 1983

/AA/ /ONEAL JONES&FELDMAN//500MG;5MG/ /N87961.001/

/MAR 17, 1983/

TABLET; ORAL

DURADYNE DHC

AA FOREST PHARM/FOREST 500MG;5MG N87809 001

MAR 17, 1983

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

> ADD > AB CORD LABORATORIES 650MG;100MG¤ N70443 001

> ADD > JAN 23, 1986

> ADD > AB LEMMON 650MG;100MG¤ N70732 001

> ADD > 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 28, 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

AMILORIDE HYDROCHLORIDE (PAGE 3-7)

TABLET; ORAL
MIDAMOR

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

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION
AMINOSYN-PF 7%

	ABBOTT LABORATORIES	7%*	N19398 001
			SEP 06, 1985

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

AMINOPHYLLINE (PAGE 3-10)

TABLET; ORAL
AMINOPHYLLINE

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

AMIODARONE HYDROCHLORIDE (PAGE 3-11)

TABLET; ORAL
CORDARONE

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

AMOXICILLIN (PAGE 3-15)

CAPSULE; ORAL
AMOXICILLIN

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

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

INJECTABLE; INJECTION
M.V.I.-12 LYOPHILIZED

	USV PHARMACEUTICAL	100MG/VIAL;0.06MG/VIAL;0.005MG/VIAL 15MG/VIAL;200 IU/VIAL;0.4MG/VIAL; 40MG/VIAL;4MG/VIAL;3.6MG/VIAL; 3MG/VIAL;3,300 IU/VIAL;10 IU/VIAL* N18933 002 AUG 08, 1985

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

INJECTABLE; INJECTION
M.V.C. 9+3

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

M.V.I.-12

AP	USV PHARMACEUTICAL	10MG/ML;0.006MG/ML;0.5UGM/ML 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 IU/ML;1 IU/ML*	N08809 004 AUG 08, 1985

MVC PLUS

AP	ASCOT HOSP PHARMS	10MG/ML;0.006MG/ML;0.5UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 IU/ML;1 IU/ML*	N18439 002 AUG 08, 1985

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

INJECTABLE; INJECTION
BEROCCA PN
HOFFMANN-LA ROCHE — 50MG/ML;0.03MG/ML;0.0025MG/ML; 7.5MG/ML;100 IU/ML;0.2MG/ML;20MG/ML; 2MG/ML;1.8MG/ML;1.5MG/ML;1,650 IU/ML; 5 IU/ML* — N06071 004 OCT 10, 1985

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)

CAPSULE; ORAL
LANORINAL
AB LANNETT — 325MG;50MG;40MG* — N86996 002 OCT 11, 1985

TABLET; ORAL
LANORINAL
AB LANNETT — 325MG;50MG;40MG* — N86986 002 OCT 18, 1985

ASPIRIN; CARISOPRODOL (PAGE 3-20)

TABLET; ORAL
CARISOPRODOL COMPOUND
AB BOLAR PHARMACEUTICAL — 325MG;200MG* — N88809 001 OCT 03, 1985

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

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 001 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

> ADD >
> ADD >
> ADD >

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

CREAM; TOPICAL
DIPROLENE
BX SCHERING — EQ 0.05% BASE* — N19408 001 JAN 31, 1986

LOTION; TOPICAL
ALPHATREX
AB SAVAGE LABS/ALTANA — EQ 0.05% BASE* — N70273 001 AUG 12, 1985

BETAMETHASONE DIPROPIONATE
AB E FOUGERA/ALTANA — EQ 0.05% BASE* — N70275 001 AUG 12, 1985

AB PHARMADERM/ALTANA — EQ 0.05% BASE* — N70274 001 AUG 12, 1985

BETAMETHASONE VALERATE (PAGE 3-26)

OINTMENT; TOPICAL
BETA-VAL
AB LEMMON — EQ 0.1% BASE* — N70069 001 DEC 19, 1985

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC
BETOPTIC
ALCON LABORATORIES — EQ 0.5% BASE* — N19270 001 AUG 30, 1985

BETHANECHOL CHLORIDE (PAGE 3-27)

TABLET; ORAL
BETHANECHOL CHLORIDE
AA SIDMAK LABORATORIES — 5MG* — N89095 001 DEC 19, 1985

AA — 50MG* — N89096 001 DEC 19, 1985

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

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

SOLUTION; INTRAPERITONEAL
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; 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

> ADD > AT	ABBOTT LABORATORIES	20MG/100ML;30MG/100ML;600MG/100ML 310MG/100ML*	N19416 001 JAN 17, 1986

CARNITINE, L- (PAGE 3-37)

TABLET; ORAL
L-CARNITINE

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

CEFAMANDOLE NAFATE (PAGE 3-37)

INJECTABLE; INJECTION
MANDOL

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

CEFAZOLIN SODIUM (PAGE3-38)

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

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

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION
TAZIDIME

AP	ELI LILLY	2GM/VIAL*	N62655 002	NOV 20, 1985
AP		2GM/VIAL*	N62640 003	NOV 20, 1985

CEFUROXIME SODIUM (PAGE 3-40)

INJECTABLE; INJECTION
ZINACEF

> ADD >	AP	GLAXO	EQ 750MG BASE/VIAL	N50558 002	OCT 19, 1983
> ADD >	AP		EQ 1.5 GM BASE/VIAL	N50559 003	OCT 19, 1986

> ADD > KEFUROX

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

> ADD > KEFUROX IN PLASTIC CONTAINER

> ADD >	AP	ELI LILLY	EQ 750MG BASE/VIAL*	N62590 001	JAN 10, 1986
> ADD >	AP		EQ 1.5GM BASE/VIAL*	N62590 002	JAN 10, 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

CHLORPROPAMIDE (PAGE 3-48)

TABLET; ORAL
CHLORPROPAMIDE

> ADD >	AB	HALSEY DRUG	100MG*	N89321 001	JAN 16, 1986
> ADD >	AB		250MG*	N88662 001	JAN 09, 1986

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL
CHLORTHALIDONE

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

CILASTATIN SODIUM; IMIPENEM (PAGE 3-50)

INJECTABLE; INJECTION
PRIMAXIN

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

CIMETIDINE 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

CLOBETASOL PROPIONATE (PAGE 3-51)

CREAM; TOPICAL
TEMOVATE

GLAXO	0.05%*	N19322 001	DEC 27, 1985

CLOBETASOL PROPIONATE (PAGE 3-51)

OINTMENT; TOPICAL
TEMOVATE

	GLAXO	0.05%*	N19323 001	DEC 27, 1985

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	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

CROMOLYN SODIUM (PAGE 3-55)

AEROSOL; INHALATION
INTAL

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

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)

TABLET; ORAL
DEXCHLORPHENIRAMINE MALEATE

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

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)

TABLET; ORAL
POLARAMINE

> ADD > AB	SCHERING	2MG	N86835 001	

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION
DEXTROSE 5% IN PLASTIC CONTAINER

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

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION
LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

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

INJECTABLE; INJECTION

> ADD >	DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER			
> ADD >	ABBOTT LABORATORIES	5GM/100ML;74.5MG/100ML; 300MG/100ML*	N18876 001	JAN 17, 1986
> ADD >	DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER			
> ADD >	ABBOTT LABORATORIES	5GM/100ML;149MG/100ML; 300MG/100ML*	N18876 002	JAN 17, 1986
> ADD >	DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.224% IN PLASTIC CONTAINER			
> ADD >	ABBOTT LABORATORIES	5GM/100ML;224MG/100ML; 300MG/100ML*	N18876 003	JAN 17, 1986
> ADD >	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER			
> ADD > AP	KENDALL MCGAW LABS	5GM/100ML;75MG/100ML; 330MG/100ML*	N18268 011	JAN 18, 1986
> ADD >	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER			
> ADD > AP	KENDALL MCGAW LABS	5GM/100ML;150MG/100ML; 330MG/100ML*	N18268 012	JAN 18, 1986

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

INJECTABLE; INJECTION

> ADD > DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE
> ADD > 0.22% IN PLASTIC CONTAINER
> ADD > KENDALL MCGAW LABS 5GM/100ML;220MG/100ML;
> ADD > 330MG/100ML¤ N18268 013
> ADD > JAN 18, 1986
> ADD > **DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE**
> ADD > **0.30% IN PLASTIC CONTAINER**
> ADD > AP KENDALL MCGAW LABS 5GM/100ML;300MG/100ML;
> ADD > 330MG/100ML¤ N18268 014
> ADD > 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 ELKINS-SINN/AHROBINS 5MG/ML¤ N70311 001
DEC 16, 1985
AP 5MG/ML¤ N70312 001
DEC 16, 1985
AP 5MG/ML¤ N70313 001
DEC 16, 1985

VALIUM

AP HOFFMANN-LA ROCHE 5MG/ML N16087 001

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

DIAZEPAM

AB BARR LABORATORIES 2MG¤ N70152 001
NOV 01, 1985
AB 5MG¤ N70153 001
NOV 01, 1985
AB 10MG¤ N70154 001
NOV 01, 1985
AB CHELSEA LABORATORIES 2MG¤ N70456 001
NOV 01, 1985
AB 5MG¤ N70457 001
NOV 01, 1985
AB 10MG¤ N70458 001
NOV 01, 1985
AB CORD LABORATORIES 2MG¤ N70302 001
DEC 20, 1985
AB 5MG¤ N70303 001
DEC 20, 1985
AB 10MG¤ N70304 001
DEC 20, 1985
AB LEDERLE LABS/AM CYAN 2MG¤ N70226 001
SEP 26, 1985
AB 5MG¤ N70227 001
SEP 26, 1985
AB 10MG¤ N70228 001
SEP 26, 1985
AB MYLAN PHARMS 2MG¤ N70323 001
SEP 04, 1985
AB 5MG¤ N70324 001
SEP 04, 1985
AB 10MG¤ N70325 001
SEP 04, 1985
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 SUPERPHARM 2MG¤ N70642 001
DEC 11, 1985
AB 5MG¤ N70643 001
DEC 11, 1985
AB 10MG¤ N70644 001
DEC 11, 1985
AB ZENITH LABORATORIES 2MG¤ N70360 001
SEP 04, 1985
AB 5MG¤ N70361 001
SEP 04, 1985
AB 10MG¤ N70362 001
SEP 04, 1985

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

	Q-PAM			
AB	QUANTUM PHARMICS	2MG¤	N70423 001	DEC 12, 1985
AB		5MG¤	N70424 001	DEC 12, 1985
AB		10MG¤	N70425 001	DEC 12, 1985
	VALIUM			
AB	HOFFMANN-LA ROCHE	2MG	N13263 002	
AB		5MG	N13263 004	
AB		10MG	N13263 006	

DICYCLOMINE HYDROCHLORIDE (PAGE 3-73)

TABLET; ORAL

	BENTYL			
AB	MERRELL DOW/DOW CHEM	20MG	N07409 001	OCT 15, 1984
	DICYCLOMINE HCL			
AB	BARR LABORATORIES	20MG	N84600 001	JUL 29, 1985

DIFLORASONE DIACETATE (PAGE 3-74)

CREAM; TOPICAL

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

DIFLORASONE DIACETATE (PAGE 3-74)

OINTMENT; TOPICAL

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

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	CORD LABORATORIES	EQ 100MG BASE¤	N70470 001	DEC 10, 1985
AB		EQ 150MG BASE¤	N70471 001	DEC 10, 1985
AB	ZENITH LABORATORIES	EQ 100MG BASE¤	N70186 001	NOV 18, 1985
AB		EQ 150MG BASE¤	N70187 001	NOV 18, 1985

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION

	DOPAMINE HCL			
AP	ASTRA PHARM PRODS	40MG/ML¤	N70087 001	OCT 23, 1985
AP		80MG/ML¤	N70089 001	OCT 23, 1985
AP		80MG/ML¤	N70090 001	OCT 23, 1985
AP		80MG/ML¤	N70091 001	OCT 23, 1985
AP		160MG/ML¤	N70092 001	OCT 23, 1985
AP		160MG/ML¤	N70093 001	OCT 23, 1985
AP		160MG/ML¤	N70094 001	OCT 23, 1985
AP	LYPHOMED	160MG/ML¤	N70364 001	DEC 04, 1985
AP	SOLOPAK LABORATORIES	40MG/ML¤	N70011 001	AUG 29, 1985
AP		40MG/ML¤	N70046 001	AUG 29, 1985
AP		80MG/ML¤	N70047 001	AUG 29, 1985
	DOPASTAT			
AP	PARKE-DAVIS/W-L	40MG/ML¤	N70558 001	SEP 20, 1985
AP		80MG/ML¤	N70559 001	SEP 20, 1985
	INTROPIN			
AP	AM CRITICAL CARE/AHS	160MG/ML	N17395 003	

DOXYCYCLINE HYCLATE (PAGE 3-79)

> ADD >		CAPSULE, COATED PELLETS; ORAL			
> ADD >		**DORYX**			
> ADD >	AB	FAULDING	EQ 100MG BASE	N50582 001	
> ADD >				JUL 22, 1985	
> ADD >	AB	PARKE-DAVIS/W-L	EQ 100MG BASE*	N62653 001	
> ADD >				OCT 30, 1985	
		CAPSULE; ORAL			
> DLT >		/DORYX/			
> DLT >	/AB/	/FAULDING/	/EQ 100MG BASE/	/N50582 001/	
> DLT >				/JUL 22, 1985/	
> DLT >	/AB/	/PARKE-DAVIS/W-L/	/EQ 100MG BASE*/	/N62653 001/	
> DLT >				/OCT 30, 1985/	
		TABLET; ORAL			
		DOXYCYCLINE HYCLATE			
	AB	PARKE-DAVIS/W-L	EQ 50MG BASE*	N62594 001	
				DEC 05, 1985	
	AB		EQ 100MG BASE*	N62954 002	
				DEC 05, 1985	
	AB		EQ 100MG BASE*	N62593 001	
				AUG 28, 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; 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	

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

FLUOCINOLONE ACETONIDE (PAGE 3-92)

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

FLUOROMETHOLONE (PAGE 3-93)

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

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

FOLIC ACID (PAGE 3-95)

TABLET; ORAL
FOLIC ACID
> ADD > AA BARR LABORATORIES 1MG¤ N89177 001 JAN 08, 1986
> ADD >
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

FUROSEMIDE (PAGE 3-96)

TABLET; ORAL
FUROSEMIDE
AB BARR LABORATORIES 20MG¤ N70043 001 SEP 26, 1985
> ADD > AB ROXANE LABORATORIES 80MG¤ N70086 001 JAN 24, 1986
> ADD >
AB WATSON LABORATORIES 20MG¤ N70449 001 NOV 22, 1985
AB 40MG¤ N70450 001 NOV 22, 1985
> ADD > AB 80MG¤ N70528 001 JAN 07, 1986
> ADD >

GENTAMICIN SULFATE (PAGE 3-97)

INJECTABLE; INJECTION
GENTAFAIR
AP PHARMAFAIR EQ 40MG BASE/ML¤ N62493 001 AUG 28, 1985

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

> ADD >	AP	ABBOTT LABORATORIES	EQ 60MG BASE/100ML 900MG/100ML¤	N62588 006 JAN 06, 1986	
> ADD >	AP		EQ 70MG BASE/100ML 900MG/100ML¤	N62588 007 JAN 06, 1986	
> ADD >	AP		EQ 80MG BASE/100ML 900MG/100ML¤	N62588 008 JAN 06, 1986	
> ADD >	AP		EQ 90MG BASE/100ML 900MG/100ML¤	N62588 009 JAN 06, 1986	
> ADD >	AP		EQ 100MG BASE/100ML 900MG/100ML¤	N62588 010 JAN 06, 1986	
> ADD >	AP		EQ 1.2MG BASE/ML;9MG/ML¤	N62588 001 JAN 06, 1986	
> ADD >	AP		EQ 1.4MG BASE/ML;9MG/ML¤	N62588 002 JAN 06, 1986	
> ADD >	AP		EQ 1.6MG BASE/ML;9MG/ML¤	N62588 003 JAN 06, 1986	
> ADD >	AP		EQ 1.8MG BASE/ML;9MG/ML¤	N62588 004 JAN 06, 1986	
> ADD >	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

> ADD > HALOPERIDOL DECANOATE (PAGE 3-102)

> ADD > INJECTABLE; INJECTION
> ADD > HALDOL DECANOATE

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

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION
/HEP-LOCK PF/

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

HEP-LOCK U/P

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

HEPARIN LOCK FLUSH

AP	CARTER-GLOGAU LABS	100 UNITS/ML	N17067 001
AP	LUITPOLD PHARMS	10 UNITS/ML¤	N89063 001 OCT 09, 1985
AP		100 UNITS/ML¤	N89064 001 OCT 09, 1985

HEPARIN SODIUM

/AP/	CARTER-GLOGAU LABS	/100 UNIT/ML/	/N17064 001/
AP		2,500 UNITS/ML	N17064 015
AP		7,500 UNITS/ML	N17064 019
		3,000 UNITS/ML	N17064 016
		4,000 UNITS/ML	N17064 017
		6,000 UNTIS/ML	N17064 018
/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/

HEXACHLOROPHANE (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

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

TABLET; ORAL
HYDRALAZINE HCL

> ADD >	AA	HALSEY DRUG	10MG¤	N89218 001	
> ADD >				JAN 22, 1986	
> ADD >	AA		25MG¤	N89130 001	
> ADD >				JAN 15, 1986	
> ADD >	AA		50MG¤	N89222 001	
> ADD >				JAN 22, 1986	
> ADD >	AA		100MG¤	N89178 001	
> ADD >				JAN 15, 1986	
	AA	SIDMAK LABORATORIES	10MG¤	N89097 001	
				DEC 18, 1985	
	AA		100MG¤	N89098 001	
				DEC 18, 1985	

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-108)

CAPSULE; ORAL
HYDRA-ZIDE

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

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)

TABLET; ORAL
ALDORIL D30

> ADD >	AB	MS&D/MERCK	30MG;500MG	N13402 003
		ALDORIL D50		
> ADD >	AB	MS&D/MERCK	50MG;500MG	N13402 004
		ALDORIL 15		
> ADD >	AB	MS&D/MERCK	15MG;250MG	N13402 001
		ALDORIL 25		
> ADD >	AB	MS&D/MERCK	25MG;250MG	N13402 002
> ADD >		**METHYLDOPA AND HYDROCHLOROTHIAZIDE**		
> ADD >	AB	CORD LABORATORIES	15MG;250MG¤	N70182 001
> ADD >				JAN 15, 1986
> ADD >	AB		25MG;250MG¤	N70183 001
> ADD >				JAN 15, 1986
> ADD >	AB		30MG;500MG¤	N70543 001
> ADD >				JAN 15, 1986
> ADD >	AB		50MG;500MG¤	N70544 001
> ADD >				JAN 15, 1986
> ADD >	AB	MYLAN PHARMS	15MG;250MG¤	N70264 001
> ADD >				JAN 23, 1986
> ADD >	AB		25MG;250MG¤	N70265 001
> ADD >				JAN 23, 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)

LOTION; TOPICAL
STIE-CORT

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

OINTMENT; TOPICAL
HYDROCORTISONE IN ABSORBASE

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

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

SUSPENSION; OTIC
NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

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

NEOMYCIN SULFATE, POLYMYXIN B SULFATE & HYDROCORTISONE

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

SUSPENSION/DROPS; OPHTHALMIC
CORTISPORIN

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

NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE

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

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

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

HYDROCORTISONE BUTYRATE (PAGE 3-116)

CREAM; TOPICAL
HYDROCORTISONE BUTYRATE
BX ◑ GIST-BROCADES 0.1% N18514 001 MAY 31, 1982

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

OINTMENT; TOPICAL
HYDROCORTISONE BUTYRATE
BX ◑ GIST-BROCADES 0.1% N18652 001 OCT 29, 1982

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

HYDROFLUMETHIAZIDE; RESERPINE (PAGE 3-117)

TABLET; ORAL
HYDROFLUMETHIAZIDE AND RESERPINE
BP PAR PHARMACEUTICAL 50MG;0.125MG¤ N88907 001 SEP 20, 1985

HYDROXYZINE HYDROCHLORIDE (PAGE 3-118)

INJECTABLE; INJECTION
HYDROXYZINE
AP ELKINS-SINN/AHROBINS 50MG/ML N85551 002
HYDROXYZINE HCL
/AP/ /ELKINS-SINN/AHROBINS/50MG/ML/ /N85551.002/

HYDROXYZINE HYDROCHLORIDE (PAGE 3-118)

TABLET; ORAL
HYDROXYZINE HCL
AB QUANTUM PHARMICS 10MG¤ N88540 001 OCT 22, 1985
AB 25MG¤ N88551 001 OCT 22, 1985
AB 50MG¤ N88529 001 OCT 22, 1985
> ADD > AB SIDMAK LABORATORIES 10MG¤ N88617 001 JAN 10, 1986
> ADD >
> ADD > AB 25MG¤ N88618 001 JAN 10, 1986
> ADD >
> ADD > AB 50MG¤ N88619 001 JAN 10, 1986
> ADD >

IBUPROFEN (PAGE 3-120)

TABLET; ORAL
IBUPROFEN
AB CHELSEA LABORATORIES 400MG¤ N70038 001 SEP 06, 1985
AB 600MG¤ N70041 001 SEP 06, 1985
AB DANBURY PHARMACAL 400MG¤ N70436 001 AUG 21, 1985
AB 600MG¤ N70437 001 AUG 21, 1985
AB MYLAN PHARMS 400MG¤ N70045 001 SEP 24, 1985
AB 600MG¤ N70057 001 SEP 24, 1985
AB OHM LABORATORIES 400MG¤ N70818 001 DEC 26, 1985
AB ◑ PAR PHARMACEUTICALS 300MG¤ N70328 001 AUG 06, 1985
AB 400MG¤ N70329 001 AUG 06, 1985
AB 600MG¤ N70330 001 AUG 06, 1985

IBUPROHM
AB OHM LABORATORIES 400MG¤ N70469 001 AUG 29, 1985

MOTRIN
AB ◑ UPJOHN 300MG N17463 003
800MG¤ N17463 005 MAY 22, 1985

INDIUM IN-111 OXYQUINOLINE (PAGE 3-121)

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

INDOMETHACIN (PAGE 3-122)

CAPSULE; ORAL
INDO-LEMMON
AB LEMMON 25MG* — N70266 001 NOV 07, 1985
AB 50MG* — N70267 001 NOV 07, 1985

INDOMETHACIN
AB DURAMED PHARMS 25MG* — N70326 001 OCT 18, 1985
AB 50MG* — N70327 001 OCT 18, 1985
AB MYLAN PHARMS 50MG* — N70624 001 SEP 04, 1985
AB WATSON LABORATORIES 25MG* — N70529 001 OCT 18, 1985
AB 50MG* — N70530 001 OCT 18, 1985

SUSPENSION; ORAL
INDOCIN
MS&D RES LABS/MERCK 25MG/5ML* — N18332 001 OCT 10, 1985

IOHEXOL (PAGE 3-123)

INJECTABLE; INJECTION
OMNIPAQUE 180
WINTHROP-BREON/STERL 38.8%* — N18956 001 DEC 26, 1985

OMNIPAQUE 240
WINTHROP-BREON/STERL 51.8%* — N18956 002 DEC 26, 1985

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

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

IOPAMIDOL (PAGE 3-123)

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

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

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

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

KETOCONAZOLE (PAGE 3-127)

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

>ADD> KETOPROFEN (PAGE 3-127)

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

LABETALOL HYDROCHLORIDE (PAGE 3-127)

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

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

LEUCOVORIN CALCIUM (PAGE 3-127)

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

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

LEVOBUNOLOL HYDROCHLORIDE (PAGE 3-128)

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

LORAZEPAM (PAGE 3-132)

TABLET; ORAL
ATIVAN
AB WYETH LABS/AMHO 0.5MG N17794 001
AB 1MG N17794 002
AB 2MG N17794 003
LORAZEPAM
AB BARR LABORATORIES 0.5MG* N70472 001 DEC 10, 1985
AB 1MG* N70473 001 DEC 10, 1985
AB 2MG* N70474 001 DEC 10, 1985
AB QUANTUM PHARMICS 0.5MG* N70200 001 AUG 09, 1985
AB 1MG* N70201 001 AUG 09, 1985
AB 2MG* N70202 001 AUG 09, 1985

LOXAPINE SUCCINATE (PAGE 3-132)

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

MANNITOL (PAGE 3-134)

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

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

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

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

MEDROXYPROGESTERONE ACETATE (PAGE 3-136)

TABLET; ORAL
PROVERA
UPJOHN 5MG N11839 003

METHOCARBAMOL (PAGE 3-142)

TABLET; ORAL
METHOCARBAMOL
AA PIONEER PHARMS 500MG* N88731 001 DEC 13, 1985
AA 750MG* N89082 001 DEC 13, 1985

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION
FOLEX
AP ADRIA LABS/ERBAMONT EQ 250MG BASE/VIAL* N88954 001 OCT 24, 1985

> ADD >
> ADD > FOLEX PFS
> ADD > AP ADRIA LABS/ERBAMONT EQ 25MG BASE/ML* N89180 001 JAN 03, 1986
> ADD >
> ADD > AP EQ 25MG BASE/ML* N89181 001 JAN 03, 1986
> ADD >
> ADD > AP EQ 25MG BASE/ML* N89182 001 JAN 03, 1986
> ADD >

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

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION
METHOTREXATE SODIUM

AP	LYPHOMED	EQ 20MG BASE/VIAL*	N88935 001	OCT 11, 1985
AP		EQ 50MG BASE/VIAL*	N88936 001	OCT 11, 1985
AP		EQ 100MG BASE/VIAL*	N89937 001	OCT 11, 1985

MEXATE

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

METHYLDOPA (PAGE 3-144)

TABLET; ORAL
METHYLDOPA

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

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-145)

INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE

>ADD> AP	QUAD PHARMS	EQ 40MG BASE/VIAL*	N89264 001	JAN 22, 1986
>ADD> AP		EQ 125MG BASE/VIAL*	N89265 001	JAN 22, 1986
>ADD> AP		EQ 500MG BASE/VIAL*	N89266 001	JAN 22, 1986
>ADD> AP		EQ 1GM BASE/VIAL*	N89267 001	JAN 22, 1986

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION
REGLAN

>ADD> AP	AH ROBINS	EQ 5MG BASE/ML	N17862 001	

METOCLOPRAMIDE HCL

>ADD> AP	LYPHOMED	EQ 5MG BASE/ML*	N70293 001	JAN 24, 1986

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

TABLET; ORAL
CLOPRA-"YELLOW"

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

METOCLOPRAMIDE HCL

>ADD> AB	DANBURY PHARMACAL	EQ 10MG BASE*	N70511 001	JAN 22, 1986
>ADD> AB	PUREPAC/KALIPHARMA	EQ 10MG BASE*	N70581 001	OCT 17, 1985

METRONIDAZOLE (PAGE 3-148)

TABLET; ORAL
METRONIDAZOLE

AB	VITARINE	250MG	N18620 001	MAR 04, 1982
AB		500MG	N18620 001	JUN 02, 1983

METRYL

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

METRYL 500

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

METRONIDAZOLE HYDROCHLORIDE (PAGE 3-148)

INJECTABLE; INJECTION
FLAGYL I.V.

AP	SEARLE PHARMS	EQ 500MG BASE/VIAL	N18353 001

METRONIDAZOLE HCL

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

MEXILETINE HYDROCHLORIDE (PAGE 3-149)

CAPSULE; ORAL
MEXITIL

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

MIDAZOLAM HYDROCHLORIDE (PAGE 3-149)

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

MONOOCTANOIN (PAGE 3-150)

LIQUID; PERFUSION, BILIARY
MOCTANIN
ASCOT HOSP PHARMS 100%¤ N19368 001
OCT 29, 1985

NABILONE (PAGE 3-150)

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

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
>ADD> AP		0.4MG/ML¤	N70639 001
			SEP 24, 1986 : JAN 17, 1986
>ADD> 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

NARCAN

AP	DUPONT PHARMS/DUPONT	0.02MG/ML	N16636 001
AP		0.4MG/ML	N16636 002
/3/		1MG/ML	N16636 003
			JUN 14, 1982

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE (PAGE 3-151)

TABLET; ORAL
TALWIN NX
~~/WINTHROP-BREON/STERL/0.5 MG;EQ 50MG BASE/ /N18733 001/~~
WINTHROP-BREON/STERL EQ 0.5MG BASE;
EQ 50MG BASE N18733 001

NIFEDIPINE (PAGE 3-154)

CAPSULE; ORAL
ADALAT

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

PROCARDIA

AB	PFIZER LABS/PFIZER	10MG	N18482 001

NITROGLYCERIN (PAGE 3-154)

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

INJECTABLE; INJECTION
NITROGLYCERIN

AP	INTL MEDICATION SYS	5MG/ML¤	N70026 001
			SEP 10, 1985
AP	LYPHOMED	5MG/ML¤	N70077 001
			DEC 13, 1985

NOMIFENSINE MALEATE (PAGE 3-155)

CAPSULE; ORAL
MERITAL

	∂ HOECHST-ROUSSEL	25MG	N18224 001
			DEC 31, 1984
>ADD>	∂	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

NYSTATIN (PAGE 3-156)

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

MYCO-TRIACET II
AT LEMMON 100,000 UNITS/GM;0.1%* N62045 002 NOV 26, 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

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

PHENTERMINE HYDROCHLORIDE (PAGE 3-167)

CAPSULE; ORAL
/ADIPEX/
/AA/ /LEMMON/ /30MG*/ N87126 001
PHENTERMINE HCL
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
>ADD> ◉ BURROUGHS WELLCOME EQ 500MG BASE N09102 003

POTASSIUM CHLORIDE (PAGE 3-171)

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

POTASSIUM CITRATE (PAGE 3-173)

TABLET; ORAL
POTASSIUM CITRATE
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 ACETATE; SULFACETAMIDE SODIUM (PAGE 3-175)

SUSPENSION/DROPS; OPHTHALMIC
BLEPHAMIDE
AT ALLERGAN PHARMS 0.2%;10% N12813 002
PREDSULFAIR II
AT PHARMAFAIR 0.2%;10%* N88837 001
DEC 24, 1985

PREDNISONE (PAGE 3-176)

TABLET; ORAL
DELTASONE
AB UPJOHN 5MG N09986 002
AB 10MG N09986 003
AB 20MG N09986 007
PREDNISONE
AB MUTUAL PHARM 5MG* N89245 001
DEC 04, 1985
AB 10MG* N89246 001
DEC 04, 1985
AB 20MG* N89247 001
DEC 04, 1985
AB WEST-WARD 10MG* N88832 001
DEC 04, 1985

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

INJECTABLE; INJECTION
PROCAINAMIDE HCL
AP PHARMAFAIR 100MG/ML* N88824 001
NOV 20, 1985
AP 500MG/ML* N88830 001
NOV 20, 1985

TABLET, CONTROLLED RELEASE; ORAL
PROCAINAMIDE HCL
AB DANBURY PHARMACAL 250MG* N89026 001
OCT 22, 1985
AB 500MG* N89027 001
OCT 22, 1985
AB 750MG* N89042 001
OCT 22, 1985
RHYTHMIN
AB SIDMAK LABORATORIES 250MG* N88958 001
DEC 02, 1985
AB 500MG* N88959 001
DEC 02, 1985

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

SYRUP; ORAL
PROMETHAZINE
AA LIFE LABORATORIES 6.25MG/5ML* N89013 001
SEP 20, 1985

TABLET; ORAL
PROMETHAZINE HCL
BP LEMMON 25MG* N89109 001
SEP 10, 1985

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL

PROPRANOLOL

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

PROPRANOLOL HCL

AB	BARR LABORATORIES	10MG*	N70319 001 OCT 22, 1985
AB		20MG*	N70320 001 OCT 22, 1985
AB		40MG*	N70103 001 OCT 22, 1985
AB	DURAMED PHARMS	10MG*	N70306 001 SEP 09, 1985
AB		20MG*	N70307 001 SEP 09, 1985
AB		40MG*	N70308 001 SEP 09, 1985
AB		80MG*	N70310 001 SEP 09, 1985
AB	MARTEC PHARMS	10MG*	N70120 001 AUG 06, 1985
AB		20MG*	N70121 001 AUG 06, 1985
AB		40MG*	N70122 001 AUG 06, 1985
AB		80MG*	N70124 001 AUG 06, 1985

QUAZEPAM (PAGE 3-186)

TABLET; ORAL

DORMALIN

	SCHERING	15MG*	N18708 001 DEC 27, 1985

QUINIDINE GLUCONATE (PAGE 3-186)

TABLET, CONTROLLED RELEASE; ORAL

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

SILVER SULFADIAZINE (PAGE 3-191)

CREAM; TOPICAL

SILVADENE

/MARION LABORATORIES/ /1%/ /N17381 001/

>DLT>	/AT/			
>ADD>	AB	MARION LABORATORIES	1%	N17381 001

SSD

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

>DLT>	/AT/			
>DLT>				
>ADD>	AB	TRAVENOL LABS	1%	N18578 001 FEB 25, 1982
>ADD>				

ULTRA DERM

>ADD>				
>ADD>	AB	CHESEBROUGH-PONDS	1%*	N18810 001 DEC 23, 1985
>ADD>				

SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-191)

GRANULE, EFFERVESCENT; ORAL

BAROS

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

SODIUM CHLORIDE (PAGE 3-191)

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	900MG/100ML*	N19480 001 SEP 17, 1985
AP	TRAVENOL LABS	9MG/ML*	N16677 004 OCT 30, 1985

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

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

SOMATREM (PAGE 3-195)

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

SOMATROPIN (PAGE 3-195)

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

CRESCORMON
◕ KABIVITRUM 4 IU/VIAL — N17992 001

SULCONAZOLE NITRATE (PAGE 3-197)

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

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

SUPROFEN (PAGE 3-201)

CAPSULE; ORAL
SUPROL
ORTHO PHARMACEUTICAL 200MG¤ — N18217 001
DEC 24, 1985

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

INJECTABLE; INJECTION
/TECHNECOLL/
/AP/ /MALLINCKRODT/ /N/A/ /N17059/001/
> DLT > /TESULOID/
> DLT >/AP/ /ER SQUIBB AND SONS/ /N/A/ /N16923.001/

SOLUTION; INJECTION, ORAL
TECHNECOLL
> ADD > AP MALLINCKRODT N/A N17059 001
> ADD >
TESULOID
> ADD > 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
AB QUANTUM PHARMICS 15MG* N70564 001
OCT 15, 1985
AB 30MG* N70547 001
OCT 15, 1985

THEOPHYLLINE (PAGE 3-206)

CAPSULE, CONTROLLED RELEASE; ORAL
THEO-DUR SPRINKLE
BC KEY PHARMACEUTICALS 50MG* N88022 001
SEP 10, 1985
BC 125MG* N88016 001
SEP 10, 1985
BC 200MG* N87995 001
SEP 10, 1985
75MG* N88015 001
SEP 10, 1985

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
> DLT > /BD/ /WILLIAM H RORER/ /100MG/ /N85202.001/
> DLT > /BD/ /200MG/ /N85204.001/

THEOPHYLLINE (PAGE 3-206)

TABLET; ORAL
> ADD > AB WILLIAM H RORER 100MG N85202 001
> ADD > AB 200MG N85204 001
THEOPHYL-225
> DLT > /KNOLL PHARMACEUTICAL/225MG/ /N84726.001/
> ADD > MCNEIL PHARM 225MG N84726 001

TABLET, CHEWABLE; ORAL
THEOPHYL
MCNEIL PHARM 100MG* N86506 001
SEP 12, 1985

THIORIDAZINE HYDROCHLORIDE (PAGE 3-209)

CONCENTRATE; ORAL
THIORIDAZINE HCL INTENSOL
AA ROXANE LABORATORIES 30MG/ML* N88941 001
DEC 16, 1985
AA 100MG/ML* N88942 001
DEC 16, 1985

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL
TOLAZAMIDE
> ADD > AB BARR LABORATORIES 100MG* N70162 001
> ADD >
JAN 14, 1986
> ADD > AB 250MG* N70163 001
> ADD >
JAN 14, 1986
> ADD > AB 500MG* N70164 001
> ADD >
JAN 14, 1986
> ADD > AB CHELSEA LABORATORIES 100MG* N70285 001
> ADD >
JAN 09, 1986
> ADD > AB 250MG* N70286 001
> ADD >
JAN 09, 1986
> ADD > AB 500MG* N70287 001
> ADD >
JAN 09, 1986
> ADD > AB DANBURY PHARMACAL 100MG* N70513 001
> ADD >
JAN 09, 1986
> ADD > AB 250MG* N70514 001
> ADD >
JAN 09, 1986
> ADD > AB 500MG* N70515 001
> ADD >
JAN 09, 1986
> ADD > AB DURAMED PHARMS 100MG* N70165 001
> ADD >
JAN 10, 1986
> ADD > AB 250MG* N70166 001
> ADD >
JAN 10, 1986
> ADD > AB 500MG* N70167 001
> ADD >
JAN 10, 1986
> ADD > AB MYLAN PHARMS 250MG* N70259 001
> ADD >
JAN 02, 1986

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL
TOLAZAMIDE

> ADD >	AB	PAR PHARMACEUTICAL	100MG*	N70159 001
> ADD >				JAN 06, 1986
> ADD >	AB		250MG*	N70160 001
> ADD >				JAN 06, 1986
> ADD >	AB		500MG*	N70161 001
> ADD >				JAN 06, 1986

TRIENTINE HYDROCHLORIDE (PAGE 3-216)

CAPSULE; ORAL
CUPRID

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

TRIMETHOPRIM (PAGE 3-218)

TABLET; ORAL
TRIMETHOPRIM

> ADD >	AB	BARR LABORATORIES	100MG*	N70494 001
> ADD >				JAN 22, 1986

TROPICAMIDE (PAGE 3-219)

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE

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

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

VINBLASTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION
VELBAN

		/ELI LILLY/	/10MG/AMP/	/N12665 001/
AP		ELI LILLY	10MG/VIAL	N12665 001

VINBLASTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION
VINBLASTINE SULFATE

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

WARFARIN SODIUM (PAGE 3-221)

TABLET; ORAL
COUMADIN

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

WARFARIN SODIUM

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

CHLORHEXIDINE GLUCONATE (PAGE 3-224)

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

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-225)

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

IBUPROFEN (PAGE 3-225)

TABLET; ORAL
IBUPROFEN
BARR LABORATORIES 200MG N70493 001 SEP 24, 1986 : DEC 24, 1985
PAR PHARMACEUTICAL 200MG N70481 001 SEP 24, 1986 : OCT 18, 1985

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

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

INSULIN, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION
> DLT > /HUMULIN N/
> DLT > /ELI LILLY/ /100 UNITS/ML/ /N18781 001/ /OCT 28, 1986/

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

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

NO SEPTEMBER - JANUARY 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 Approved and Denied List

5. Exclusivity Terms

6. Prescription and OTC Drug Product Patent and Exclusivity Data

APPENDIX I

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

The Orphan Drug Act amendments, which provide incentives to encourage the development of orphan drugs and biological products, became effective on January 4, 1983.

Section 526 of the 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 NDA or license approval for a designated orphan drug. The period of exclusivity may be revoked during the seven year period by written consent of the sponsor or by FDA action after finding that the sponsor holding exclusivity cannot assure the availability of sufficient quantities of the drug to meet the needs of patients with the designated orphan indication.

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

For the following drug products with orphan drug exclusive approval status, the sponsor has seven years of exclusivity for the approved indication beginning on the date of NDA or biological license approval for the drug. No subsequent sponsor may receive approval of an NDA, Biological License, paper NDA, or ANDA during the seven year period.

Biologicals, Antibiotics or Drugs that have been approved under Section 505 of the 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.

BIOLOGICAL PRODUCTS

Active Ingred.(s) Strength	Trade Name Dosage Form; Route	Applicant	License Number Approval Date	Exclusivity Exp.Date
Hemin 313mg/amp	Panhematin Injectable; Injection	Abbott Laboratories	43 Jul 20, 1983	ODE Jul 20, 1990

APPENDIX 1

DRUG PRODUCTS

Active Ingred.(s) Strength(s)	Trade Name Dosage Form; Route	Applicant	Appl. Prod. Approval Date	Exclusivity Exp. Date
Chenodiol 250mg	Chenix Tablet; Oral	Rowell Laboratories	18513 002 Jul 28, 1983	ODE Jul 28, 1990
L-Carnitine 330mg	L-Carnitine Tablet; Oral	Sigma-Tau	18948 001 Dec 27, 1985	ODE Dec 27, 1992
Pentamidine Isethionate 300mg/ml	Pentam 300 Injectable; Injection	LyphoMed	19264 001 Oct 16, 1984	ODE Oct 16, 1991
Naltrexone Hydrochloride 50mg	Trexan Tablet; Oral	Dupont Pharms	18932 001 Nov 20, 1984	ODE Nov 20, 1991
Potassium Citrate 5meq	Urocit-K Tablet; Oral	Univ of Tx Hlth Sci Ctr	19071 001 Aug 30, 1985	ODE Aug 30, 1992
Monooctanoin 100%	Moctanin Liquid; Perfusion Biliary	Ascot Hosp Pharms	19368 001 Oct 29, 1985	ODE Oct 29, 1992

(continued)

APPENDIX 1

DRUG PRODUCTS

(continued)

Active Ingred.(s) Strength(s)	Trade Name Dosage Form; Route	Applicant	Appl. Prod. Approval Date	Exclusivity Exp. Date
Somatrem 5mg/vial	Protropin Injectable; Injection	Genentech	19107 001 Oct 17, 1985	ODE Oct 17, 1992
Trientine Hydrochloride 250mg	Cuprid Capsule; Oral	Merck Sharp and Dohme Res Labs	19194 001 Nov 8, 1985	ODE Nov 08, 1992

APPENDIX 2

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

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

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

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

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

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

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

Aminophylline
Tablet; Oral
100mg
200mg

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

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

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

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

Aspirin; Carisoprodol
Tablet; Oral
325mg; 200mg

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

Aspirin; Meprobamate
Tablet; Oral
325mg; 200mg

Aspirin; Methocarbamol
Tablet; Oral
325mg; 200mg

Chlorothiazide
Tablet; Oral
250mg

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

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

APPENDIX 3

BIOPHARMACEUTIC GUIDANCE AVAILABILITY LIST

The following is a list of guidances available for *in vivo* bioequivalence studies and *in vitro* dissolution testing available from the Division of Bioequivalence, HFN-250, Room 18B-31, 5600 Fishers Lane, Rockville, MD 20857.

Name of Drug	Date
Acetohexamide	Nov 15, 1985
Allopurinol	Jul 15, 1985
Amiloride Hydrochloride	Mar 29, 1985
Aminophylline Suppositories	Jul 05, 1983
Amitriptyline Hydrochloride	Jul 05, 1983
Anticholinergic Drugs (Controlled Release)	Nov 07, 1980
Carbamazepine	Dec 05, 1984
Chlordiazepoxide Hydrochloride	Jul 05, 1983
Chlorpropamide	Jul 05, 1983
Chlorthalidone	Jul 05, 1983
Clonidine Hydrochloride	Dec 05, 1984
Diazepam (revised)	Jul 08, 1985
Dicyclomine Hydrochloride	Aug 10, 1984
Dipyridamole	Jul 05, 1983
Disopyramide Phosphate	Jul 09, 1985
Dissolution Testing (General)	Apr 19, 1983
Doxepin Hydrochloride	Apr 02, 1985
Erythromycin	Apr 05, 1977
Flurazepam	Oct 15, 1985
Hydrochlorothiazide	Jul 25, 1983

(continued)

APPENDIX 3

(continued)

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

APPENDIX 4

ANDA SUITABILITY PETITIONS

The following are two lists of Petitions filed under Section 505(j)(2)(C) of the Act where the Agency has determined that the referenced product: (1) is suitable for submission as an ANDA (List I., Petitions Approved) and (2) is not suitable for submission as an ANDA (List II., Petitions Denied). The determination that an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency. A copy of each petition is listed by docket number on public display in FDA's Dockets Management Branch, HFA-305, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

I. Petitions Approved

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Acetaminophen; Hydrocodone Bitartrate Solution; Oral	500mg/15ml 5mg/15ml	84 P-0391/CP	New Dosage Form	Approved Jul 2, 1985
Acetaminophen; Oxycodone Hydrochloride Solution; Oral	325mg/5ml 5mg/5ml	85 P-0085/CP	New Dosage Form	Approved Aug 23, 1985
Acetaminophen 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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Aminophylline Injectable; Injection	10mg/ml 10ml/vial	85 P-0459/CP	New Strength	Approved Feb 12, 1986
Aminophylline Injectable; Injection	50mg/ml 20ml/vial	85 P-0459/CP	New Strength	Approved Feb 12, 1986
Azatadine Maleate; Phenylpropanolamine Hydrochloride Sustained Release Capsule; Oral	1mg 75mg	85 P-0492/CP	New Combination New Dosage Form	Approved Jan 28, 1986
Benztropine Mesylate Syrup; Oral	0.5mg/5ml	85 P-0423/CP	New Dosage Form	Approved Oct 16, 1985
Brompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	12mg 120mg	85 P-0095/CP	New Combination New Dosage Form	Approved Dec 13, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Chlorpheniramine Maleate; Phenylpropanolamine Hydrochloride Controlled-release Capsule; Oral	10mg 75mg	85 P-0149/CP	New Strength	Approved Dec 13, 1985
Chlorhexidine Gluconate Solution; Topical	1.5%	84 P-0417/CP	New Strength	Approved Sep 18, 1985
Codeine Phosphate; Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Syrup; Oral	10mg/5ml 1mg/5ml 12.5mg/5ml	85 P-0269/CP	New Combination	Approved Dec 6, 1985
Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Time Release Capsule; Oral	6mg 75mg	85 P-0238/CP0002	New Combination	Approved Dec 13, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Dexbrompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/CP	New Combination New Dosage Form	Approved Dec 13, 1985
Dexbrompheniramine Maleate; Pseudoephedrine Sulfate Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/ CP0002	New Dosage Form	Approved Jan 22, 1986
Diazepam Solution; Oral	5mg/5ml	85 P-0090/CP	New Dosage Form	Approved Sep 19, 1985
Diphenhydramine Hydrochloride Concentrate; Oral	50mg/ml	84 P-0174/CP	New Strength	Approved Sep 11, 1985
Disulfiram Suspension; Oral	500mg/30ml	85 P-0215/CP	New Dosage Form	Approved Oct 8, 1985
Fluorouracil Injectable; Injection	25mg/ml	85 P-0208/CP	New Strength	Approved Oct 8, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Nitroglycerin Injectable; Injection	10mg/ml	85 P-0134/CP	New Strength	Approved Sep 19, 1985
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
Propranolol Hydrochloride Solution; Oral	40mg/5ml	85 P-0073/CP	New Dosage Form	Approved Jul 8, 1985
Propranolol Hydrochloride Concentrate; Oral	80mg/ml	85 P-0073/ CP0002	New Dosage Form	Approved Jul 19, 1985
Propranolol Hydrochloride Solution; Oral	20mg/5ml	85 P-0073/ CP0003	New Dosage Form	Approved Sep 24, 1985
Propranolol Hydrochloride Tablet; Constant-Release; Oral	160mg	85 P-0129/CP	New Dosage Form	Approved Sep 25, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Propranolol Hydrochloride Tablet, Controlled Release; Oral	80mg 120mg 160mg	85 P-0197/CP	New Dosage Form	Approved Sep 27, 1985
Pyridostigmine Bromide Tablet; Oral	30mg	85 P-0412/CP	New Strength	Approved Jan 22, 1986
Scopolamine Transdermal System/24 Hour Film, Controlled Release; Percutaneous	1mg	85 P-0168/CP	New Strength (Dosing Interval)	Approved Sep 27, 1985
Spironolactone Syrup; Oral	25mg/5ml	85 P-0510/CP	New Dosage Form	Approved Jan 22, 1986
Theophylline Capsule; Oral	150mg 300mg	85 P-0175/CP	New Strength	Approved Oct 8, 1985
Vincristine Sulfate Injectable; Injection	2mg/vial	85 P-0016/CP	New Dosage Form	Approved Nov 8, 1985

APPENDIX 4

II. Petitions Denied

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 30mg	85 P-0101/CP	New Combination	Denied Sep 11, 1985
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 60mg	85 P-0101/ CP0002	New Combination	Denied Sep 11, 1985
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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
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
Heparin Sodium Injectable; Injection	4000 Units/ml	85 P-0065/CP	New Strength	Denied May 29, 1985
Ibuprofen; Oxycodone Hydrochloride Capsule; Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985
Ibuprofen; Oxycodone Hydrochloride Tablet; Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985
Indomethacin Tablet, Constant Release; Oral	75mg	85 P-0026/CP	New Dosage Form	Denied Sep 16, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0062/CP	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0062/ CP0002	New Strength	Denied May 29, 1985
Metronidazole Sponge; Vaginal	50-125mg/ Sponge	85 P-0117/CP	New Dosage Form	Denied Oct 8, 1985
Nitroglycerin Transdermal System	None Given	84 P-0302/CP	New Dosage Form (New Matrix)	Denied Jul 29, 1985
Phenylephrine Hydrochloride; Sulfathiazole Nasal Suspension; Topical	0.5% 5%	85 P-0205/CP	New Dosage Form New Combination	Denied Nov 14, 1985
Triamcinolone Acetonide Suspension; Injection	2.5mg/ml	85 P-0001/CP	New Strength	Denied Mar 4, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 5

(continued)

NEW INDICATION

I-1	SEVERE HYPERTENSION IN PEDIATRICS AND NON-MALIGNANT HYPERTENSION
I-2	DYSMENORRHEA
I-3	TREATMENT OF TINEA VERSICOLOR
I-4	SYMPTOMATIC GASTROESOPHAGEAL REFLUX
I-5	NEPHROTOMOGRAPHY
I-6	CONTRAST ENHANCEMENT IN CRANIAL COMPUTED TOMOGRAPHY
I-7	VENOGRAPHY OF LOWER EXTREMITIES
I-8	WHOLE-BODY COMPUTED TOMOGRAPHY
I-9	GATED CARDIAC POOL IMAGING
I-10	POST-MYOCARDIAL INFARCTION
I-11	COLORECTAL SURGERY
I-12	NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY
I-13	CISPLATIN INDUCED EMESIS
I-14	DIABETIC GASTROPARESIS
I-15	SHORT TERM TREATMENT OF GASTRIC ULCER DISEASE
I-16	ACROMEGALY
I-17	PITUITARY TUMORS
I-18	POSTMENOPAUSAL OSTEOPOROSIS
I-19	ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
I-20	CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE
I-21	ACUTE/OTITIS/MEDIA
I-22	EXERCISE INDUCED BRONCHOSPASMS
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

(continued)

APPENDIX 5

(continued)

NEW INDICATION

	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
> ADD >	I-41	MANAGEMENT OF HYPOCALCEMIA AND RESULTANT METABOLIC BONE DISEASE IN RENAL DIALYSIS PATIENTS

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 - JANUARY ACTIONS

APPENDIX 6

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
>ADD>	12142 001	4537883	AUG 27, 2002		
>ADD>	12142 002	4537883	AUG 27, 2002		
	12142 003	4537883	AUG 27, 2002		
	12142 004	4537883	AUG 27, 2002		
	12142 005	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
	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, 1965		
		3717647	FEB 20, 1990		
	17613 001	3839573	OCT 01, 1991		
	17619 001	3839573	OCT 01, 1991		
	17666 001	4324779	APR 13, 1999		
	17760 001			NDF	SEP 04, 1988
	17768 001	3855140	DEC 17, 1991	I-38	SEP 24, 1986
		3960745	DEC 17, 1991		
	17717 001	3839573	OCT 01, 1991		
	17862 001	4536386	AUG 20, 2002		
	17970 001	4536516	AUG 20, 2002	I-39	DEC 10, 1988

(continued)

(continued)

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

(continued)

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
> ADD >	18044 001			I-41	JAN 22, 1989
> ADD >	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		
	18181 001	/3839573/	/OCT/01,/1991/		
	18182 001	/3839573/	/OCT/01,/1991/		
	18183 001	/3839573/	/OCT/01,/1991/		
	18217 001	4035376	JUL 12, 1994	NCE	DEC 24, 1990
	18230 001	/3839573/	/OCT/01,/1991/		
	18240 001			I-35	SEP 04, 1988
	18240 002			I-35	SEP 04, 1988
	18401 001	3433791	MAR 18, 1986		
	18423 001	3855140	DEC 17, 1991		
		3960745	DEC 17, 1991		
	18482 001	3784684	JAN 08, 1991		
	18506 001	/3419565/	/DEC/31,/1985/		
		/3717647/	/FEB/20,/1990/		
	18509 001			NP	AUG 07, 1988
	18513 002			ODE	JUL 28, 1990
	18587 003	3658993	APR 25, 1989	NCE	SEP 07, 1992
	18644 001	3819706	JUN 25, 1991	NCE	DEC 30, 1990
		3885046	MAY 20, 1992		
		4057323	MAR 26, 2002		
		4347257	AUG 31, 1999		
		4393078	JUL 12, 2000		
		4425363	JAN 10, 2001		
		4435449	MAR 06, 2001		
		4438138	MAR 20, 2001		
	18644 002	3819706	JUN 25, 1991	NCE	DEC 30, 1990
		3885046	MAY 20, 1992		
		4057323	MAR 26, 2002		
		4347257	AUG 31, 1999		
		4393078	JUL 12, 2000		
		4425363	JAN 10, 2001		
		4435449	MAR 06, 2001		
		4438138	MAR 20, 2001		
	18644 003	3819706	JUN 25, 1991	NCE	DEC 30, 1990
		3885046	MAY 20, 1992		
		4057323	MAR 26, 2002		
		4347257	AUG 31, 1999		
		4393078	JUL 12, 2000		
		4425363	JAN 10, 2001		
		4435449	MAR 06, 2001		
		4438138	MAR 20, 2001		
	18654 001	4280957	JUL 28, 1998	NCE	DEC 20, 1990
	18677 001	4087545	MAY 02, 1995	NCE	DEC 26, 1990
		4087547	MAY 02, 1995		
	18683 001	4393871	JUL 19, 2000		
> ADD >	18701 001	3438991	APR 15, 1986	NE	JAN 14, 1989
	18703 002	4128658	DEC 05, 1995	NCE	JUN 09, 1993
		4521431	JUN 04, 2002	I-15	JUN 28, 1988

(continued)

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

(continued)

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	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
>ADD>	18754 002	3641127	FEB 08, 1989	NCE	JAN 09, 1991
>ADD>	18754 003	3641127	FEB 08, 1989	NCE	JAN 09, 1991
	18813 001	/3839573/	/OCT/01,/1991/		
	18827 001	/3839573/	/OCT/01,/1991/		
	18830 001	3900481	AUG 19, 1992	NCE	OCT 31, 1990
	18830 001	4005209	JAN 25, 1994	NCE	OCT 31, 1990
	18830 002	3900481	AUG 19, 1992	NCE	OCT 31, 1990
	18830 002	4005209	JAN 25, 1994	NCE	OCT 31, 1990
	18859 001	4211771	JUL 08, 1997	NCE	DEC 31, 1990
		RE29835	MAR 19, 1991		
	18873 002	3954872	MAY 04, 1993	NCE	DEC 30, 1990
		4031244	JUN 21, 1994		
	18873 003	3954872	MAY 04, 1993	NCE	DEC 30, 1990
		4031244	JUN 21, 1994		
	18873 004	3954872	MAY 04, 1993	NCE	DEC 30, 1990
		4031244	JUN 21, 1994		
>ADD>	18887 001	3686412	AUG 22, 1989	NDF	DEC 05, 1988
>ADD>		3777033	AUG 22, 1989		
>ADD>	18891 001	4559222	DEC 17, 2002		
>ADD>	18891 002	4559222	DEC 17, 2002		
>ADD>	18891 003	4559222	DEC 17, 2002		
	18928 001	4221778	SEP 09, 1997		
	18932 001			ODE	NOV 20, 1991
	18948 001			NCE	DEC 27, 1990
				ODE	DEC 27, 1992
	18949 001	/3806526/	/APR/23,/1991/		
		/3965257/	/JUN/22,/1993/		
		/3966949/	/JUN/29,/1993/		
		/4254129/	/MAR/03,/1998/		
		/4285957/	/AUG/25,/1998/		

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	18956 001	4021481	MAY 03, 1994	NCE	DEC 26, 1990
		4250113	FEB 10, 1998		
	18956 002	4021481	MAY 03, 1994	NCE	DEC 26, 1990
		4250113	FEB 10, 1998		
	18956 003	4021481	MAY 03, 1994	NCE	DEC 26, 1990
		4250113	FEB 10, 1998		
	18956 004	4021481	MAY 03, 1994	NCE	DEC 26, 1990
		4250113	FEB 10, 1998		
	18972 001			NCE	DEC 24, 1990
	18985 001	4544554	JUL 23, 2002		
	18985 002	4544554	JUL 23, 2002		
	18998 001	4374829	FEB 22, 2000	NCE	DEC 24, 1990
	18998 002	4374829	FEB 22, 2000	NCE	DEC 24, 1990
	18998 003	4374829	FEB 22, 2000	NCE	DEC 24, 1990
	19011 001			NP	SEP 24, 1986
>DLT>	/19644/001/	/4335059/	/JUN/15,/1999/	/NCE/	/DEC/23,/1990/
>ADD>	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
	19084 001	4335125	JUN 15, 1999	NDF	DEC 31, 1988
	19107 001			NCE	OCT 17, 1990
	19107 001			ODE	OCT 17, 1992
	19194 001			NCE	NOV 11, 1990
				ODE	NOV 11, 1992
	19215 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990
	19219 002	3641152	FEB 08, 1989	NCE	DEC 19, 1990
	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		

(continued)

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

(continued)

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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
19425 001	4012444	MAR 15, 1994	NCE	AUG 01, 1994
	4066755	JAN 03, 1995		
19434 001	3950333	APR 13, 1993		
	4024271	MAY 17, 1994		
19478 001	3644627	FEB 22, 1989		
	3784684	JAN 08, 1991		