CUMULATIVE SUPPLEMENT 6 AUG'85-FEB'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

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

B. ACTIVITY FOR SUPPLEMENT NUMBER 6

	FEB '86	CUMULATIVE
DRUG PRODUCTS ADDED:	59	59
NEWLY APPROVED	59	59
DESI EFFECTIVE	0	0
REMARKETED	0	0
DRUG PRODUCTS REMOVED:	0	0
WITHDRAWN APPROVAL	0	0
RX TO OTC SWITCH	0	0
NET GAIN IN DRUG PRODUCTS	59	59
SINGLE SOURCE PRODUCTS APPROVED	6	6
MULTISOURCE DRUG PRODUCTS APPROVED	53	53
NEW MOLECULAR ENTITIES APPROVED:	0	0
AS THE ENTITY	0	0
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	0

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

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

B. DRUG PRODUCT LISTS

1. Prescription Drug Product List

2. OTC Drug Product List

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

ACETAMINOPHEN; 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
MEDIGESIC PLUS
AB US CHEM MKTG GROUP 325MG;50MG;40MG* N89115 001 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
> ADD > AA MIKART 300MG;30MG* N89238 001
> ADD > FEB 25, 1986
AA SUPERPHARM 300MG;30MG* N89184 001 OCT 18, 1985
ACETAMINOPHEN AND CODEINE PHOSPHATE #4
> ADD > AA MIKART 300MG;60MG* N89244 001
> ADD > FEB 25, 1986
AA SUPERPHARM 300MG;60MG* N89185 001 OCT 18, 1985
ACETAMINOPHEN W/ CODEINE
/AA/ /VITARINE/ /300MG;30MG/ /N85917.001/
ACETAMINOPHEN W/ CODEINE #2
/AA/ /VITARINE/ /300MG;15MG/ /N87433.001/
ACETAMINOPHEN W/ CODEINE #4
/AA/ /VITARINE/ /300MG;60MG/ /N87423.001/

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL
ACETAMINOPHEN AND HYDROCODONE BITARTRATE
AA DH 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/
> ADD > HYDROCODONE BITARTRATE AND ACETAMINOPHEN
> ADD > AA MIKART 500MG;5MG* N89008 001
> ADD > FEB 21, 1986

TABLET; ORAL
DURADYNE DHC
AA FOREST PHARM/FOREST 500MG;5MG N87809 001 MAR 17, 1983

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
AB 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/25,/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
> DLT > /NOV/30,/1988/ DEC 10, 1985
AB 300MG* N70147 001
> DLT > /NOV/30,/1988/ DEC 10, 1985

AMILORIDE HYDROCHLORIDE (PAGE 3-7)

TABLET; ORAL
MIDAMOR
AB MSD/MERCK 5MG N18200 001
AMILORIDE HCL
AB PAR PHARMACEUTICAL 5MG* N70346 001
JAN 22, 1986

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION
AMINOSYN-PF 7%
ABBOTT LABORATORIES 7%* N19398 001
SEP 06, 1985

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

INJECTABLE; INJECTION
/TRAVASOL/M/3.5%/W/ELECTROLYTE/45/
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
/EP/ /CORD LABORATORIES/ /100MG/ /N85262/002/

AMIODARONE HYDROCHLORIDE (PAGE 3-11)

TABLET; ORAL
CORDARONE
IVES LABS/AMNO 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

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.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

ASPIRIN; METHOCARBAMOL (PAGE 3-20)

TABLET; ORAL

METHOCARBAMOL AND ASPIRIN

> ADD > AB MCNEIL CONSUMER PROD 325MG;400MG* N89193 001 FEB 12, 1986
> ADD >

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

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

CREAM; TOPICAL

DIPROLENE

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

LOTION; TOPICAL

ALPHATREX

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

BETAMETHASONE DIPROPIONATE

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

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

BETAMETHASONE VALERATE (PAGE 3-26)

OINTMENT; TOPICAL

BETA-VAL

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

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC

BETOPTIC

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

BETHANECHOL CHLORIDE (PAGE 3-27)

TABLET; ORAL
BETHANECHOL CHLORIDE
AA SIDMAK LABORATORIES 5MG* N89095 001 DEC 19, 1985
AA 50MG* N89096 001 DEC 19, 1985

BRETYLIUM TOSYLATE (PAGE 3-28)

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE
AP LYPHOMED 50MG/ML* N70134 001 APR 29, 1986 : FEB 12, 1986
BRETYLOL
AP AM CRITICAL CARE/AHS 50MG/ML N17954 001

BUPIVACAINE HYDROCHLORIDE; DEXTROSE (PAGE 3-29)

INJECTABLE; INJECTION
MARCAINE SPINAL
@ WINTHROP-BREON/STERL 0.75%;8.25% N18592 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

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; 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

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

SOLUTION; IRRIGATION
LACTATED RINGER'S IN PLASTIC CONTAINER

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

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION
TAZIDIME

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

CEFUROXIME SODIUM (PAGE 3-40)

INJECTABLE; INJECTION
ZINACEF

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

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

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

> ADD >					
> ADD >	BC	BF ASCHER	12MG;75MG*	N88359 001	FEB 13, 1986
> ADD >					

ORNADE

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

CHLORPROPAMIDE (PAGE 3-48)

TABLET; ORAL
CHLORPROPAMIDE

AB	HALSEY DRUG	100MG*	N39321 001	JAN 16, 1986
AB		250MG*	N88662 001	JAN 09, 1986

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL
CHLORTHALIDONE

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

CILASTATIN SODIUM; IMIPENEM (PAGE 3-50)

INJECTABLE; INJECTION
PRIMAXIN

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

CIMETIDINE 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

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* N18837 001 DEC 05, 1985

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)

TABLET; ORAL
DEXCHLORPHENIRAMINE MALEATE
AB SIDMAK LABORATORIES 2MG* N88682 001 JAN 17, 1986

FOLARAMINE
AB SCHERING 2MG N86835 001

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION
DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABORATORIES 5GM/100ML* N19479 001 SEP 17, 1985
AP TRAVENOL LABS 50MG/ML* N16673 003 OCT 30, 1985

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION
LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABORATORIES 5GM/100ML;200MG/100ML* N18954 001 JUL 09, 1985

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

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

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

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

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

INJECTABLE; INJECTION
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

> ADD >	AP	CARTER-GLOGAU LABS	5MG/ML#	N70296 001	
> ADD >				FEB 12, 1986	
	AP	ELKINS-SINN/AHROBINS	5MG/ML#	N70311 001	
				DEC 16, 1985	
	AP		5MG/ML#	N70312 001	
				DEC 16, 1985	
	AP		5MG/ML#	N70313 001	
				DEC 16, 1985	

VALIUM

AP	HOFFMANN-LA ROCHE	5MG/ML	N16087 001	

TABLET; ORAL

DIAZEPAM

AB	BARR LABORATORIES	2MG#	N70152 001	
			NOV 01, 1985	
AB		5MG#	N70153 001	
			NOV 01, 1985	
AB		10MG#	N70154 001	
			NOV 01, 1985	
AB	CHELSEA LABORATORIES	2MG#	N70456 001	
			NOV 01, 1985	
AB		5MG#	N70457 001	
			NOV 01, 1985	
AB		10MG#	N70458 001	
			NOV 01, 1985	
AB	CORD LABORATORIES	2MG#	N70302 001	
			DEC 20, 1985	
AB		5MG#	N70303 001	
			DEC 20, 1985	
AB		10MG#	N70304 001	
			DEC 20, 1985	
AB	LEDERLE LABS/AM CYAN	2MG#	N70226 001	
			SEP 26, 1985	
AB		5MG#	N70227 001	
			SEP 26, 1985	
AB		10MG#	N70228 001	
			SEP 26, 1985	
AB	MYLAN PHARMS	2MG#	N70323 001	
			SEP 04, 1985	
AB		5MG#	N70324 001	
			SEP 04, 1985	
AB		10MG#	N70325 001	
			SEP 04, 1985	
> ADD > AB	PAR PHARMACEUTICAL	2MG#	N70462 001	
> ADD >			FEB 25, 1986	
> ADD > AB		5MG#	N70463 001	
> ADD >			FEB 25, 1986	
> ADD > AB		10MG#	N70464 001	
> ADD >			FEB 25, 1986	

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

DIAZEPAM

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	

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*	N88680 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
> ADD > AB	BOLAR PHARMACEUTICAL	EQ 100MG BASE*	N70240 001 FEB 02, 1986
> ADD > 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

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION
DOPAMINE HCL

AP	ASTRA PHARM PROD	160MG/ML*	N70094 001 OCT 23, 1985

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION
DOPAMINE HCL

AP	LYPHOMED	160MG/ML*	N70364 001 DEC 04, 1985
AP	SOLOPAK LABORATORIES	40MG/ML*	N70011 001 AUG 29, 1985
AP		40MG/ML*	N70046 001 AUG 29, 1985
AP		80MG/ML*	N70047 001 AUG 29, 1985

DOPASTAT

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

INTROPIN

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

DOXYCYCLINE HYCLATE (PAGE 3-79)

CAPSULE, COATED PELLETS; ORAL
DORYX

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

CAPSULE; ORAL
/DORYX/

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

INJECTABLE; INJECTION
DOXYCYCLINE HYCLATE

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

DOXYCYCLINE HYCLATE (PAGE 3-79)

TABLET; ORAL
DOXYCYCLINE HYCLATE

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

	MSD RES LABS/MERCK	5MG‡	N18993 001	DEC 24, 1985
		10MG‡	N18993 002	DEC 24, 1985
		20MG‡	N18993 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

FLUOROMETHOLONE (PAGE 3-93)

SUSPENSION/DROPS; OPHTHALMIC

> ADD >		FLUOR-OP			
> ADD >	AB	COOPERVISION PHARMS	0.1%*	N70185 001	FEB 27, 1986
> ADD >					
		FML			
> ADD >	AB	ALLERGAN PHARMS	0.1%	N16851 002	JUL 28, 1982

> ADD > FLUOROMETHOLONE ACETATE (PAGE 3-93)

SUSPENSION/DROPS; OPHTHALMIC

> ADD >		OMNITROL			
> ADD >		ALCON LABORATORIES	0.1%*	N19079 001	FEB 11, 1986
> ADD >					

FLUPHENAZINE DECANOATE (PAGE 3-94)

INJECTABLE; INJECTION

> ADD >		FLUPHENAZINE			
> ADD >	AO	QUAD PHARMS	25MG/ML*	N70762 001	FEB 20, 1986
> ADD >					
		PROLIXIN DECANOATE			
> ADD >	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

> DLT > /FOLATE SODIUM/(PAGE 3-95)

> DLT > /INJECTABLE; INJECTION/
> DLT > /FOLVITE/
> DLT > /LEDERLE LABS/AM CYAN/5MG BASE/ML/ /N05897 000/

FOLIC ACID (PAGE 3-95)

> ADD > INJECTABLE; INJECTION
> ADD > FOLIC ACID

> ADD > AP	LYPHOMED	5MG/ML*	N89202 001	FEB 18, 1986
> ADD >				
> ADD >	FOLVITE			
> ADD > 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
> ADD > AP	SOLOPAK LABORATORIES	10MG/ML*	N70023 001	FEB 05, 1986
> ADD >				
> ADD > AP		10MG/ML*	N70078 001	FEB 05, 1986
> ADD >				

TABLET; ORAL
FUROSEMIDE

AB	BARR LABORATORIES	20MG*	N70043 001	SEP 26, 1985
> ADD > AB	DANBURY PHARMACAL	20MG*	N70412 001	FEB 26, 1986
> ADD >				
> ADD > AB		40MG*	N70413 001	FEB 26, 1986
> ADD >				
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 (PAGE 3-97)

INJECTABLE; INJECTION
GENTAMICIN SULFATE

> ADD >	AP	ABBOTT LABORATORIES	EQ 10MG BASE/ML¤	N62612 004
> ADD >				FEB 20, 1986
	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/	N16522 001
			/FEB/19,/1982/

GLYCINE 1.5% IN PLASTIC CONTAINER

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

GUANABENZ ACETATE (PAGE 3-102)

TABLET; ORAL
WYTENSIN

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

HALOPERIDOL DECANOATE (PAGE 3-102)

INJECTABLE; INJECTION
HALDOL DECANOATE

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

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION
/HEP-LOCK/PF/

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

HEP-LOCK U/P

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

HEPARIN LOCK FLUSH

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

HEPARIN SODIUM

/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

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/

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

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

INJECTABLE; INJECTION
HYDRALAZINE HCL

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

TABLET; ORAL
HYDRALAZINE HCL

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

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-108)

CAPSULE; ORAL
HYDRA-ZIDE

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

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)

TABLET; ORAL
ALDORIL D30

AB	MS&D/MERCK	30MG;500MG	N13402 003	

ALDORIL D50

AB	MS&D/MERCK	50MG;500MG	N13402 004	

ALDORIL 15

AB	MS&D/MERCK	15MG;250MG	N13402 001	

ALDORIL 25

AB	MS&D/MERCK	25MG;250MG	N13402 002	

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	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

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	MYLAN PHARMS	15MG;250MG*	N70264 001	JAN 23, 1986
AB		25MG;250MG*	N70265 001	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/
/FEINVALT PHARM/ /EQ 5MG BASE/5ML;/ /EQ 10MG BASE/5ML/ /N10768 006/

HYDROCORTISONE (PAGE 3-112)

CREAM; TOPICAL
HYDROCORTISONE

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

LOTION; TOPICAL
HYDROCORTISONE

> ADD > 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

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

SUSPENSION; OTIC
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/	
> ADD > AP	PHARMAFAIR	25MG/ML*	N88862 001	FEB 14, 1986
> ADD >				
> ADD > AP		25MG/ML*	N89106 001	FEB 14, 1986
> ADD >				
> ADD > AP		50MG/ML*	N89107 001	FEB 14, 1986
> ADD >				
> ADD > AP		50MG/ML*	N88881 001	FEB 14, 1986
> ADD >				

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
AB	SIDMAK LABORATORIES	10MG*	N88617 001	JAN 10, 1986
AB		25MG*	N88618 001	JAN 10, 1986
AB		50MG*	N88619 001	JAN 10, 1986

IBUPROFEN (PAGE 3-120)

TABLET; ORAL
IBUPROFEN

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

IBUPROFEN (PAGE 3-120)

TABLET; ORAL

	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
> ADD > AB	ZENITH LABORATORIES	25MG*	N70719 001	FEB 12, 1986
> ADD >				
> ADD > AB		50MG*	N70756 001	FEB 12, 1986
> ADD >				

SUSPENSION; ORAL

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

IOHEXOL (PAGE 3-123)

INJECTABLE; INJECTION

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

IOHEXOL (PAGE 3-123)

INJECTABLE; INJECTION

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

IOPAMIDOL (PAGE 3-123)

INJECTABLE; INJECTION

ISOVUE-300			
ER SQUIBB AND SONS	61%*	N18735 002	DEC 31, 1985
ISOVUE-370			
ER SQUIBB AND SONS	76%*	N18735 003	DEC 31, 1985
ISOVUE-M 200			
ER SQUIBB AND SONS	41%*	N18735 001	DEC 31, 1985
ISOVUE-M 300			
ER SQUIBB AND SONS	61%*	N18735 004	DEC 31, 1985

ISONIAZID (PAGE3-125)

SYRUP; ORAL

> ADD >				
> ADD > AA	LANIAZID			
> ADD >	LANNETT	50MG/5ML*	N89243 001	FEB 03, 1986

KANAMYCIN SULFATE (PAGE 3-126)

INJECTABLE; INJECTION

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

KETOCONAZOLE (PAGE 3-127)

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

KETOPROFEN (PAGE 3-127)

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

LABETALOL HYDROCHLORIDE (PAGE 3-127)

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

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

LEUCOVORIN CALCIUM (PAGE 3-127)

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

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

LEVOBUNOLOL HYDROCHLORIDE (PAGE 3-128)

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

LORAZEPAM (PAGE 3-132)

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

LORAZEPAM (PAGE 3-132)

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

MANNITOL (PAGE 3-134)

SOLUTION; IRRIGATION
RESECTISOL
/AM MCGAN/AM HOSP/ /5GM/100ML/ /N16772/002/
RESECTISOL IN PLASTIC CONTAINER
AM MCGAN/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
	FOLEX PFS			
AP	ADRIA LABS/ERBAMONT	EQ 25MG BASE/ML*	N89180 001	JAN 03, 1986
AP		EQ 25MG BASE/ML*	N89181 001	JAN 03, 1986
AP		EQ 25MG BASE/ML*	N89182 001	JAN 03, 1986
	METHOTREXATE LPF			
AP	LEDERLE LABS/AM CYAN	EQ 25MG BASE/ML	N11719 007	MAR 31, 1982
	METHOTREXATE SODIUM			
AP	LYPHOMED	EQ 20MG BASE/VIAL*	N88935 001	OCT 11, 1985
AP		EQ 50MG BASE/VIAL*	N88936 001	OCT 11, 1985
AP		EQ 100MG BASE/VIAL*	N89937 001	OCT 11, 1985
	MEXATE			
AP	BRISTOL LABS/B-M	EQ 250MG BASE/VIAL	N86358 004	

METHYCLOTHIAZIDE (PAGE 3-143)

TABLET; ORAL

		METHYCLOTHIAZIDE			
>ADD>	AB	PAR PHARMACEUTICAL	2.5MG*	N89135 001	FEB 12, 1986
>ADD>					
>ADD>	AB		5MG*	N89136 001	FEB 12, 1986
>ADD>					

METHYLDOPA (PAGE 3-144)

TABLET; ORAL

		METHYLDOPA			
>ADD>	AB	BOLAR PHARMACEUTICAL	125MG*	N70245 001	FEB 25, 1986
>ADD>					
>ADD>	AB		250MG*	N70246 001	FEB 25, 1986
>ADD>					
>ADD>	AB		500MG*	N70247 001	FEB 25, 1986
>ADD>					
	AB	LEDERLE LABS/AM CYAN	125MG*	N70070 003	OCT 15, 1985
	AB		250MG*	N70084 001	OCT 15, 1985
	AB		500MG*	N70085 001	OCT 15, 1985
>ADD>	AB	PUREPAC/KALIPHARMA	125MG*	N70749 001	FEB 07, 1986
>ADD>					
>ADD>	AB		250MG*	N70750 001	FEB 07, 1986
>ADD>					
>ADD>	AB		500MG*	N70452 001	FEB 07, 1986
>ADD>					
>ADD>	AB	ZENITH LABORATORIES	250MG*	N70098 001	FEB 20, 1986
>ADD>					
>ADD>	AB		500MG*	N70343 001	FEB 20, 1986
>ADD>					

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

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION

	REGLAN			
AP	AH ROBINS	EQ 5MG BASE/ML	N17862 001	
	METOCLOPRAMIDE HCL			
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			
AB	DANBURY PHARMACAL	EQ 10MG BASE*	N70511 001	JAN 22, 1986
AB	PUREPAC/KALIPHARMA	EQ 10MG BASE*	N70581 001	OCT 17, 1985

METRONIDAZOLE (PAGE 3-148)

TABLET; ORAL

	METRONIDAZOLE			
> ADD > AB	HALSEY DRUG	500MG*	N70593 001	FEB 27, 1986
> ADD > AB	VITARINE	250MG	N18620 001	MAR 04, 1982
AB		500MG	N18620 002	JUN 02, 1983
	METRYL			
/AB/	/VITARINE/	/250MG/	/N18620 001/	/MAR 04, 1982/
	METRYL 500			
/AB/	/VITARINE/	/500MG/	/N18620 002/	/JUN 02, 1983/

METRONIDAZOLE HYDROCHLORIDE (PAGE 3-148)

INJECTABLE; INJECTION

	FLAGYL I.V.			
AP	SEARLE PHARMS	EQ 500MG BASE/VIAL	N18353 001	
	METRONIDAZOLE HCL			
AP	LYPHOMED	EQ 500MG BASE/VIAL*	N70295 001	OCT 15, 1985

MEXILETINE HYDROCHLORIDE (PAGE 3-149)

CAPSULE; ORAL

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

MIDAZOLAM HYDROCHLORIDE (PAGE 3-149)

INJECTABLE; INJECTION

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

MONOOCTANOIN (PAGE 3-150)

LIQUID; PERFUSION, BILIARY

MOCTANIN			
ASCOT HOSP PHARMS	100%*	N19368 001	OCT 29, 1985

NABILONE (PAGE 3-150)

CAPSULE; ORAL

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

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
	NARCAN			
AP	DUPONT PHARMS/DUPONT	0.02MG/ML	N16636 001	
AP		0.4MG/ML	N16636 002	
/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 50 MG BASE/~~		~~/N18733 001/~~	
	WINTHROP-BREON/STERL	EQ 0.5MG BASE; EQ 50MG BASE	N18733 001	

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION

	NANDROLONE DECANOATE			
> ADD > AO	LEMMON	50MG/ML*	N88554 001	FEB 10, 1986
> ADD >				
> ADD > AO		50MG/ML	N87598 001	OCT 06, 1983

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
	∂	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; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

OINTMENT; TOPICAL

NYSTATIN AND TRIAMCINOLONE ACETONIDE

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

NYSTATIN-TRIAMCINOLONE ACETONIDE

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

/ANTIPEX/

/AA/	/LEMION/	/30MG/	N87126 001

PHENTERMINE HCL

AA	LEMION	30MGN	N87777 001 NOV 01, 1985
AA		30MG	N87126 001

PHENYLBUTAZONE (PAGE 3-168)

CAPSULE; ORAL

PHENYLBUTAZONE

AB	BARR LABORATORIES	100MGN	N88994 001 DEC 04, 1985

TABLET; ORAL

PHENYLBUTAZONE

AB	BARR LABORATORIES	100MGN	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/5MLN	N88815 001 NOV 22, 1985

PHENYTOIN SODIUM, EXTENDED (PAGE 3-169)

CAPSULE; ORAL

/EXTENDED PHENYTOIN SODIUM/

/AA/	/BOLAR PHARMACEUTICAL/100MG/		/N88711 001 DEC 21, 1984/

/SETTOL/

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

POTASSIUM CHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

AP	NAURRY BIOLOGICAL	2MEQ/MLN	N88286 001 SEP 05, 1985

POTASSIUM CITRATE (PAGE 3-173)

TABLET; ORAL

POTASSIUM CITRATE

	UNIV TX HLTH SCI CTR	5MEQN	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

>ADD>		MURO PHARMACEUTICAL	15MG/5ML*	N09081 001 FEB 04, 1986

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-175)

SUSPENSION/DROPS; OPHTHALMIC

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

PREDNISONE (PAGE 3-176)

TABLET; ORAL

		DELTASONE		
AB		UPJOHN	5MG	N09986 002
AB			10MG	N09986 006
AB			20MG	N09986 007
		PREDNISONE		
AB		MUTUAL PHARM	5MG*	N89245 001 DEC 04, 1985
AB			10MG*	N89246 001 DEC 04, 1985
AB			20MG*	N89247 001 DEC 04, 1985
AB		WEST-WARD	10MG*	N88832 001 DEC 04, 1985

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

INJECTABLE; INJECTION
PROCAINAMIDE HCL

>ADD>	AP	ABBOTT LABORATORIES	100MG/ML*	N89069 001 FEB 12, 1986
>ADD>	AP		500MG/ML*	N89070 001 FEB 12, 1986
	AP	PHARMAFAIR	100MG/ML*	N88824 001 NOV 20, 1985
	AP		500MG/ML*	N88830 001 NOV 20, 1985
		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

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

TABLET, CONTROLLED RELEASE; ORAL
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

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL

	PROPRANOLOL HCL		
AB	MARTEC PHARMS	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

> ADD >	QUINALAN		
> ADD > BC	LANNETT	324MG‡	N88081 001 FEB 10, 1986
> ADD >			
	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		
/AT/	/MARION LABORATORIES/	/1%/	/N17381 001/
AB	MARION LABORATORIES	1%	N17381 001

SILVER SULFADIAZINE (PAGE 3-191)

CREAM; TOPICAL

	SSD		
/AT/	/TRAVENOL LABS/	/1%/	/N18578 001/ /FEB 25, 1982/
AB	TRAVENOL LABS	1%	N18578 001 FEB 25, 1982
	ULTRA DERM		
AB	CHESEBROUGH-PONDS	1%‡	N18810 001 DEC 23, 1985

SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-191)

GRANULE, EFFERVESCENT; ORAL

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

SODIUM CHLORIDE (PAGE 3-191)

INJECTABLE; INJECTION

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

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

CAPSULE; ORAL

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

SOMATREM (PAGE 3-195)

INJECTABLE; INJECTION

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

SOMATROPIN (PAGE 3-195)

INJECTABLE; INJECTION

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

SULCONAZOLE NITRATE (PAGE 3-197)

SOLUTION; TOPICAL
SULCOSYN

	SYNTEX LABS/SYNTEX	1%*	N18738 001	AUG 30, 1985

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

SUSPENSION; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	PLANTEX/IKAPHARM	200MG/5ML;40MG/5ML*	N70028 001	JUN 02, 1987 : OCT 29, 1985

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	PHARM BASICS	400MG;80MG*	N70203 001	JUN 02, 1987 : NOV 08, 1985
AB		800MG;160MG*	N70204 001	JUN 02, 1987 : NOV 08, 1985
AB	SIDMAK LABORATORIES	400MG;80MG*	N70215 001	/JUN 02, 1987 :/SEP 10, 1985
AB		800MG;160MG	N70216 001	/JUN 02, 1987 :/SEP 10, 1985

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

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

SULFAMETHOXAZOLE AND TRIMETHOPRIM SINGLE STRENGTH

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

SULFANILAMIDE (PAGE 3-199)

CREAM; VAGINAL
VAGITROL

	LEMMON	15%*	N88718 001	SEP 19, 1985

SULFINPYRAZONE (PAGE 3-200)

CAPSULE; ORAL
SULFINPYRAZONE

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

TABLET; ORAL
SULFINPYRAZONE

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

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/	

/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

AB	QUANTUM PHARMICS	15MG*	N70564 001	OCT 15, 1985
AB		30MG*	N70547 001	OCT 15, 1985

THEOPHYLLINE (PAGE 3-206)

CAPSULE, CONTROLLED RELEASE; ORAL
THEO-DUR SPRINKLE

BC	KEY PHARMACEUTICALS	50MG*	N88022 001	SEP 10, 1985
BC		125MG*	N88016 001	SEP 10, 1985
BC		200MG*	N87995 001	SEP 10, 1985
		75MG*	N88015 001	SEP 10, 1985

ELIXIR; ORAL
THEOPHYL 225

>DLT>	/KIDD PHARMACEUTICAL/	/112.5MG/15ML/	/N86485 001/	
>ADD>	MCNEIL PHARM	112.5MG/15ML	N86485 001	

THEOPHYLLINE (PAGE 3-206)

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
/BP/ /WILLIAM H RORER/ /100MG/ /N85202 001/
/BP/ /200MG/ /N85204 001/
AB WILLIAM H RORER 100MG N85202 001
AB 200MG N85204 001

THEOPHYL-225
/KNOLL PHARMACEUTICAL/225MG/ /N84726 001/
MCNEIL PHARM 225MG N84726 001

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

THIORIDAZINE HYDROCHLORIDE (PAGE 3-209)

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

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL
TOLAZAMIDE
AB BARR LABORATORIES 100MG* N70162 001 JAN 14, 1986
AB 250MG* N70163 001 JAN 14, 1986
AB 500MG* N70164 001 JAN 14, 1986
AB CHELSEA LABORATORIES 100MG* N70285 001 JAN 09, 1986
AB 250MG* N70286 001 JAN 09, 1986
AB 500MG* N70287 001 JAN 09, 1986

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL
TOLAZAMIDE
AB DANBURY PHARMACAL 100MG* N70513 001 JAN 09, 1986
AB 250MG* N70514 001 JAN 09, 1986
AB 500MG* N70515 001 JAN 09, 1986
AB DURAMED PHARMS 100MG* N70165 001 JAN 10, 1986
AB 250MG* N70166 001 JAN 10, 1986
AB 500MG* N70167 001 JAN 10, 1986
AB MYLAN PHARMS 250MG* N70259 001 JAN 02, 1986
AB PAR PHARMACEUTICAL 100MG* N70159 001 JAN 06, 1986
AB 250MG* N70160 001 JAN 06, 1986
AB 500MG* N70161 001 JAN 06, 1986

TRIENTINE HYDROCHLORIDE (PAGE 3-216)

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

TRIMETHOPRIM (PAGE 3-218)

TABLET; ORAL
TRIMETHOPRIM
AB BARR LABORATORIES 100MG* N70494 001 JAN 22, 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
> ADD > AB ABBOTT LABORATORIES 250MG N18081 001
> ADD >
VALPROIC ACID
> ADD > AB PAR PHARMACEUTICAL 250MG* N70431 001 FEB 28, 1986
> ADD >

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/	/1MG/AMP/	/N12665 001/
AP	ELI LILLY	10MG/VIAL	N12665 001
	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

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

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

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-225)

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

DOXYLAMINE SUCCINATE (PAGE 3-225)

> ADD > CAPSULE; ORAL
> ADD > UNISOM
> ADD > 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
PAR PHARMACEUTICAL 200MG* N70481 001 SEP 24, 1986 : OCT 18, 1985
> ADD > MEDIPREN
> ADD > MCNEIL CONSUMER PROD 200MG* N70475 001 SEP 24, 1986 : FEB 06, 1986

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
/HUMULIN N/
/ELI LILLY/ /100 UNITS/ML/ /N18781 001/ /OCT 28, 1986/

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

INJECTABLE; INJECTION
HUMULIN N
ELI LILLY 100 UNITS/ML N18781 001 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 - FEBRUARY 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 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 I

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
Diazepam Syrup; Oral	2mg/5ml	85 P-0499/CP	New Dosage Form	Approved Feb 28, 1986
Diphenhydramine Hydrochloride Concentrate; Oral	50mg/ml	84 P-0174/CP	New Strength	Approved Sep 11, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

APPENDIX 4

I. Petitions Approved

(continued)

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

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
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 - FEBRUARY 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		
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, 1985		
	3717647	FEB 20, 1990		
17613 001	3839573	OCT 01, 1991		
17619 001	3839573	OCT 01, 1991		
17688 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

APPENDIX 6

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

(continued)

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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/		
	/4166347/	/JUL/11;/1995/		
	/3927002/	/DEC/16;/1992/		
18147 003	/RE29668/	/DEC/10;/1991/		
	/4166347/	/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		
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)

APPENDIX 6

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
18754 002	3641127	FEB 08, 1989	NCE	JAN 09, 1991
18754 003	3641127	FEB 08, 1989	NCE	JAN 09, 1991
18813 001	/3839573/	/OCT/01;/1991/		
18827 001	/3839573/	/OCT/01;/1991/		
18830 001	3900481	AUG 19, 1992	NCE	OCT 31, 1990
18830 001	4005209	JAN 25, 1994	NCE	OCT 31, 1990
18830 002	3900481	AUG 19, 1992	NCE	OCT 31, 1990
18830 002	4005209	JAN 25, 1994	NCE	OCT 31, 1990
18859 001	4211771	JUL 08, 1997	NCE	DEC 31, 1990
	RE29835	MAR 19, 1991		
18873 002	3954872	MAY 04, 1993	NCE	DEC 30, 1990
	4031244	JUN 21, 1994		
18873 003	3954872	MAY 04, 1993	NCE	DEC 30, 1990
	4031244	JUN 21, 1994		
18873 004	3954872	MAY 04, 1993	NCE	DEC 30, 1990
	4031244	JUN 21, 1994		
18887 001	3686412	AUG 22, 1989	NDF	DEC 05, 1988
	3777033	AUG 22, 1989		
18891 001	4559222	DEC 17, 2002		
18891 002	4559222	DEC 17, 2002		
18891 003	4559222	DEC 17, 2002		
18928 001	4221778	SEP 09, 1997		
18932 001			ODE	NOV 20, 1991
18948 001			NCE	DEC 27, 1990
			ODE	DEC 27, 1992
18949 001	/3866526/	/APR/23;/1991/		
	/3965257/	/JUN/22;/1993/		
	/3966949/	/JUN/29;/1993/		
	/4254129/	/MAR/03;/1998/		
	/4285957/	/AUG/25;/1998/		

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
18956 001	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998		
18956 002	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998		
18956 003	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998		
18956 004	4021481	MAY 03, 1994	NCE	DEC 26, 1990
	4250113	FEB 10, 1998		
18972 001			NCE	DEC 24, 1990
18985 001	4544554	JUL 23, 2002		
18985 002	4544554	JUL 23, 2002		
18998 001	4374829	FEB 22, 2000	NCE	DEC 24, 1990
18998 002	4374829	FEB 22, 2000	NCE	DEC 24, 1990
18998 003	4374829	FEB 22, 2000	NCE	DEC 24, 1990
19011 001			NP	SEP 24, 1986
/19044/001/	/4335059/	/JUN/15;/1999/	/NCE/	/DEC/23;/1990/
19044 001	4335095	JUN 15, 1999	NCE	DEC 23, 1990
19059 001	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
19059 002	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
19059 003	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
19069 001	/3839573/	/OCT/01;/1991/		
19071 001			ODE	AUG 30, 1992
			NP	AUG 30, 1988
>ADD< 19079 001			NE	FEB 11, 1989
19084 001	4335125	JUN 15, 1999	NDF	DEC 31, 1988
19107 001			NCE	OCT 17, 1990
19107 001			ODE	OCT 17, 1992
19194 001			NCE	NOV 11, 1990
			ODE	NOV 11, 1992
19215 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990
19219 002	3641152	FEB 08, 1989	NCE	DEC 19, 1990
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)

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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		