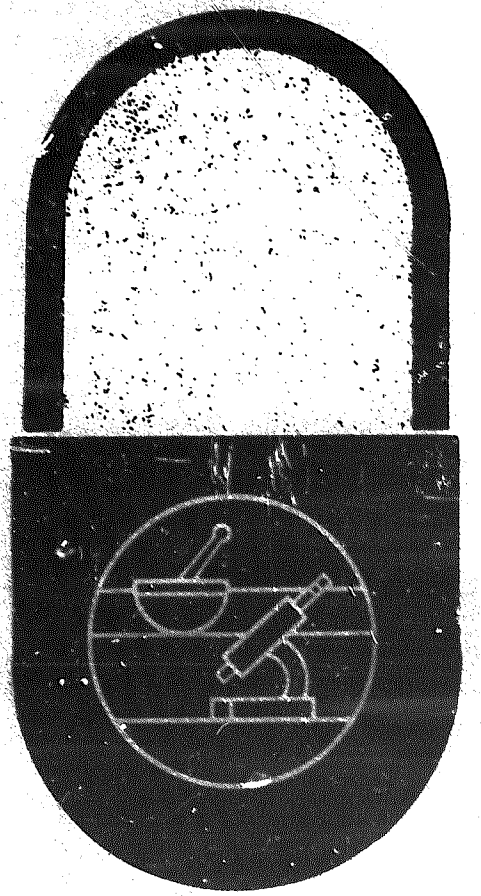
CUMULATIVE SUPPLEMENT 15

AUG '85-NOV '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

NOVEMBER 1986

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CUMULATIVE SUPPLEMENT

NOVEMBER 1986

A. INTRODUCTION

1. HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

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

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

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

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

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

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

2. APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

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

(continued)

APPLICANT (NAME) CHANGES

(continued)

Former Applicant (Name)	New Applicant (Name)	New Abbreviated Name
IVES LABS/AMHO	WYETH LABORATORIES, INC DIVISION OF AMERICAN HOME PRODUCTS CORP	WYETH LABS/AMHO
REID PROVIDENT LABS AND ROWELL LABORATORIES	REID-ROWELL	REID-ROWELL
BAY LABORATORIES	MY-K LABORATORIES, INC	MY-K LABS
AMERICAN CRITICAL CARE DIV AMERICAN HOSP SUPPLY CORP	AM CRITICAL CARE/AHS	DUPONT CRIT CARE

3. PREDNISONE BIOEQUIVALENCE

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

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

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

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

4. OTC DRUG PRODUCTS

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

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

5. PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

Products	Federal Register Reference
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)
nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (ointment;topical)	SEP 3, 1986 (51 FR 31371)
nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

6. INJECTABLE PRODUCT PACKAGE SIZE DESIGNATION

When a new drug product (usually injectable) is approved for the same concentration but a different package size than the listed drug, and it has received a period of exclusivity by the Agency, the product will appear as single source (no therapeutic equivalence code displayed) and the potency will reflect the unique package size. Once the period of exclusivity has ended, the product will then conform to the standard ADP format of reflecting "collapsed" package sizes. The current standard is to display package sizes of all small volume parenterals within an NDA as a per ml concentration and large volume parenterals as per 100ml.

7. REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Thus, products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods.

The counts appear in two sections. Section A. provides baseline and quarterly data. The baseline column refers to the products in the List. For each three-month period following July '85, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count. Section B. refers to products in the Cumulative Supplements and provides monthly activity with a cumulative count for the current quarter.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product, provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or part of a combination.

USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved and remarketed drug products which are added to the List; (2) products that are being removed from the List as the result of withdrawal of approval and changes from prescription to over-the-counter status; and, (3) trends in approval of products as either multisource or single source during each month within the quarter. The report does not reflect category changes from multisource to single source and vice versa. However, the net gain that results from all additions, deletions and category changes is reflected in the quarterly counts for multisource and single source products.

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

CATEGORIES COUNTED	JULY '85 (BASELINE)	JUL '86	OCT '86
DRUG PRODUCTS LISTED	8048	8860	9066
SINGLE SOURCE	2096 (26.0%)	2137 (24.1%)	2128 (23.5%)
MULTISOURCE(1)	5952 (74.0%)	6723 (75.9%)	6938 (76.5%)
THERAPEUTICALLY EQUIVALENT	4864 (60.5%)	5619 (63.4%)	5850 (64.5%)
NOT THERAPEUTICALLY EQUIVALENT	1054 (13.1%)	1062 (12.1%)	1039 (11.5%)
EXCEPTIONS(2)	34 (0.4%)	42 (0.4%)	49 (0.5%)
NEW MOLECULAR ENTITIES APPROVED	-	27	8
NUMBER OF APPLICANTS	306	327	330

B. ACTIVITY FOR SUPPLEMENT NUMBER 15

	NOV '86	CUMULATIVE
DRUG PRODUCTS ADDED:	81	81
NEWLY APPROVED	80	80
DESI EFFECTIVE	0	0
REMARKETED	1	1
DRUG PRODUCTS REMOVED:	0	0
WITHDRAWN APPROVAL	0	0
RX TO OTC SWITCH	0	0
NET GAIN IN DRUG PRODUCTS	81	81
SINGLE SOURCE PRODUCTS APPROVED	7	7
MULTISOURCE DRUG PRODUCTS APPROVED	74	74
NEW MOLECULAR ENTITIES APPROVED:	0	0
AS THE ENTITY	0	0
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	0

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

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

B. DRUG PRODUCT LISTS

1. Prescription Drug Product List

2. OTC Drug Product List

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

ACETAMINOPHEN (PAGE 3-1)

INJECTABLE; INJECTION
INJECTAPAP

	MCNEIL PHARM	100MG/ML*	N17785 001	MAR 07, 1986

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

CAPSULE; ORAL
BANCAP

	FOREST PHARM/FOREST	325MG;50MG*	N88889 001	JAN 16, 1986

TABLET; ORAL
SEDAPAP-10

	MAYRAND	650MG;50MG*	N88944 001	OCT 17, 1985

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL
ACETAMINOPHEN, BUTALBITAL, AND CAFFEINE

AB	MIKART	325MG;50MG;40MG*	N89007 001	MAR 17, 1986

ANOQUAN

AB	MALLARD	325MG;50MG;40MG*	N87628 001	OCT 01, 1986

MEDIGESIC PLUS

AB	US CHEM MKTG GROUP	325MG;50MG;40MG*	N89115 001	JAN 14, 1986

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE (PAGE 3-1)

CAPSULE; ORAL
COMPAL

AA	REID-ROWELL	356.4MG;30MG;16MG*	N88584 001	MAR 04, 1986

SYNALGOS-DC-A

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

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL
ACETAMINOPHEN AND CODEINE

AA	VITARINE	300MG;15MG	N87433 001	
AA		300MG;30MG	N85917 001	
AA		300MG;60MG	N87423 001	

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA	MIKART	650MG;30MG*	N89231 001	MAR 03, 1986

ACETAMINOPHEN AND CODEINE PHOSPHATE #2

AA	SUPERPHARM	300MG;15MG*	N89183 001	OCT 18, 1985

ACETAMINOPHEN AND CODEINE PHOSPHATE #3

AA	MIKART	300MG;30MG*	N89238 001	FEB 25, 1986
AA	PUREPAC/KALIPHARMA	300MG;30MG*	N89080 001	JUL 17, 1986
AA	SUPERPHARM	300MG;30MG*	N89184 001	OCT 18, 1985
AA		300MG;30MG*	N89253 001	MAY 19, 1986

ACETAMINOPHEN AND CODEINE PHOSPHATE #4

AA	MIKART	300MG;60MG*	N89244 001	FEB 25, 1986
AA	SUPERPHARM	300MG;60MG*	N89185 001	OCT 18, 1985
AA		300MG;60MG*	N89254 001	MAY 19, 1986

ACETAMINOPHEN W/ CODEINE

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

ACETAMINOPHEN W/ CODEINE #2

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

ACETAMINOPHEN W/ CODEINE #4

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

PHENAPHEN-650 W /CODEINE

AA	AH ROBINS	650MG;30MG	N85856 001	

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL
ACETAMINOPHEN AND HYDROCODONE BITARTRATE

AA	DM GRAHAM LABS	500MG;5MG*	N89006 001	AUG 09, 1985

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL

	DANCAP HC			
AA	FOREST PHARM/FOREST	500MG;5MG	N87961 001	MAR 17, 1983
/AA/	/ONEAL JONES&FELDMAN/	/500MG;5MG/	/N87961 001/	/MAR 17, 1983/
	HYDROCODONE BITARTRATE AND ACETAMINOPHEN			
AA	MIKART	500MG;5MG‡	N89008 001	FEB 21, 1986

TABLET; ORAL

	DURADYNE DHC			
AA	FOREST PHARM/FOREST	500MG;5MG	N87809 001	MAR 17, 1983
	HYDROCODONE BITARTRATE AND ACETAMINOPHEN			
AA	MIKART	500MG;5MG‡	N89271 001	JUL 16, 1986
	NORGET			
AA	HOLLOWAY PHARMS	500MG;5MG‡	N88871 001	MAY 15, 1986
	TYCODONE			
AA	MCNEIL PHARM	500MG;5MG‡	N89385 001	AUG 27, 1986

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL

/PROVOCET 100/				
	PROPACET 100			
AB	LEMMON	650MG;100MG	N70107 001	JUN 12, 1985
	PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN			
AB	BARR LABORATORIES	650MG;100MG‡	N70615 001	MAR 21, 1986
AB		650MG;100MG‡	N70771 001	MAR 21, 1986
AB		650MG;100MG‡	N70775 001	MAR 21, 1986
AB	CORD LABORATORIES	650MG;100MG‡	N70443 001	JAN 23, 1986
AB	LEMMON	650MG;100MG‡	N70732 001	JAN 03, 1986
AB	ZENITH LABORATORIES	650MG;100MG‡	N70146 001	AUG 02, 1985

ACETAZOLAMIDE (PAGE 3-4)

TABLET; ORAL

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

ACETIC ACID, GLACIAL (PAGE 3-4)

SOLUTION/DROPS; OTIC

	BOROFAIR			
AT	PHARMAFAIR	2%‡	N88506 001	AUG 21, 1985

ACETOHEXAMIDE (PAGE 3-4)

TABLET; ORAL

> ADD >	**ACETOHEXAMIDE**			
> ADD > AB	COLMED LABORATORIES	250MG‡	N70753 001	NOV 03, 1986
> ADD > AB		500MG‡	N70754 001	NOV 03, 1986
> ADD >	**DYMELOR**			
> ADD > AB	ELI LILLY INDSTRS/PR	250MG	N13378 002	
> ADD > AB		500MG	N13378 001	

ACETYLCYSTEINE (PAGE 3-5)

SOLUTION; INHALATION

	MUCOMYST			
AN	MEAD JOHNSON/B-M	10%	N13601 002	
AN		20%	N13601 001	
	MUCOSOL-10			
AN	DEY LABORATORIES	10%‡	N70575 001	OCT 14, 1986
	MUCOSOL-20			
AN	DEY LABORATORIES	20%‡	N70576 001	OCT 14, 1986

ACYCLOVIR (PAGE 3-5)

CAPSULE; ORAL

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

ALBUTEROL SULFATE (PAGE 3-6)

TABLET; ORAL

	PROVENTIL			
AB	SCHERING	EQ 2MG BASE	N17853 001	MAY 07, 1982
AB		EQ 4MG BASE	N17853 002	MAY 07, 1982
	VENTOLIN			
AB	GLAXO	EQ 2MG BASE‡	N19112 001	JUL 10, 1986
AB		EQ 4MG BASE‡	N19112 002	JUL 10, 1986

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	MYLAN PHARMS	100MG		N18659 001
				OCT 24, 1986
AB		300MG		N18659 002
				OCT 24, 1986
AB	PAR PHARMACEUTICAL	100MG		N70150 001
			/NOV 30, 1988 :	DEC 10, 1985
AB		300MG		N70147 001
			/NOV 30, 1988 :	DEC 10, 1985
AB	PUREPAC/KALIPHARMA	100MG		N70579 001
				APR 14, 1986
AB		300MG		N70580 001
				APR 14, 1986
AB	SUPERPHARM	100MG		N70950 001
			NOV 30, 1988 :	SEP 04, 1986
AB		300MG		N70951 001
			NOV 30, 1988 :	SEP 04, 1986

AMANTADINE HYDROCLORIDE (PAGE 3-7)

CAPSULE; ORAL
AMANTADINE HCL

AB	FORMUTEC	100MG		N70589 001
				AUG 05, 1986
AB	REID-ROWELL	100MG		N71000 001
				SEP 04, 1986

SYMMETREL

AB	DUPONT PHARMS/DUPONT	100MG		N16020 001
AB		100MG		N17117 001

AMILORIDE HYDROCHLORIDE (PAGE 3-7)

TABLET; ORAL
AMILORIDE HCL

AB	PAR PHARMACEUTICAL	5MG		N70346 001
				JAN 22, 1986

MIDAMOR

AB	MS&D/MERCK	5MG		N18200 001

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-7)

TABLET; ORAL
HYDRO-RIDE

AB	PAR PHARMACEUTICAL	5MG;50MG		N70347 001
			DEC 25, 1990 :	AUG 06, 1986

MODURETIC 5-50

AB	MS&D/MERCK	5MG;50MG		N18201 001

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION
AMINOSYN-HBC 7% IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	7%	N19400 001
			JUL 23, 1986

AMINOSYN-PF 7%

	ABBOTT LABORATORIES	7%	N19398 001
			SEP 06, 1985

AMINOSYN-PF 10%

	ABBOTT LABORATORIES	10%	N19492 001
			OCT 17, 1986

AMINOSYN II 3.5%

	ABBOTT LABORATORIES	3.5%	N19438 001
			APR 03, 1986

AMINOSYN II 3.5% IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	3.5%	N19491 001
			OCT 10, 1986

AMINOSYN II 5%

	ABBOTT LABORATORIES	5%	N19438 002
			APR 03, 1986

AMINOSYN II 7%

	ABBOTT LABORATORIES	7%	N19438 003
			APR 03, 1986

AMINOSYN II 8.5%

	ABBOTT LABORATORIES	8.5%	N19438 004
			APR 03, 1986

AMINOSYN II 10%

	ABBOTT LABORATORIES	10%	N19438 005
			APR 03, 1986

>ADD>	NOVAMINE 15%			
>ADD>	KABIVITRUM	15%		N17957 004
>ADD>				NOV 28, 1986

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

INJECTABLE; INJECTION

/PERIPHRAMINE/
PROCALAMINE

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

AMINO ACIDS; DEXTROSE (PAGE 3-8)

INJECTABLE;INJECTION

> ADD > AMINOSYN II 3.5% IN DEXTROSE 5% IN PLASTIC CONTAINER
> ADD > ABBOTT LABORATORIES 3.5%;5GM/100ML¤ N19506 001
> ADD > NOV 07, 1986
> ADD > AMINOSYN II 3.5% IN DEXTROSE 25% IN PLASTIC CONTAINER
> ADD > ABBOTT LABORATORIES 3.5%;25GM/100ML¤ N19505 001
> ADD > NOV 07, 1986
> ADD > AMINOSYN II 4.25% IN DEXTROSE 25% IN PLASTIC CONTAINER
> ADD > ABBOTT LABORATORIES 4.25%;25GM/100ML¤ N19504 002
> ADD > NOV 07, 1986

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

INJECTABLE; INJECTION

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

AMINOSYN II 3.5% M IN PLASTIC CONTAINER
ABBOTT LABORATORIES 3.5%;32MG/100ML;128MG/100ML; 222MG/100ML;49MG/100ML¤ N19493 001
OCT 16, 1986

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

INJECTABLE; INJECTION

AMINOSYN II 7% W/ ELECTROLYTES
ABBOTT LABORATORIES 7%;102MG/100ML;45MG/100ML; 522MG/100ML;410MG/100ML¤ N19437 006
APR 03, 1986

AMINOSYN II 8.5% W/ ELECTROLYTES
ABBOTT LABORATORIES 8.5%;102MG/100ML;45MG/100ML; 522MG/100ML;410MG/100ML¤ N19437 005
APR 03, 1986

AMINOSYN II 10% W/ ELECTROLYTES
ABBOTT LABORATORIES 10%;102MG/100ML;45MG/100ML; 522MG/100ML;410MG/100ML¤ N19437 004
APR 03, 1986

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

INJECTABLE; INJECTION

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

AMINOCAPROIC ACID (PAGE 3-9)

INJECTABLE; INJECTION

AMINOCAPROIC ACID
AP LYPHOMED 250MG/ML¤ N70522 001
JUN 17, 1986
AP QUAD PHARMS 250MG/ML¤ N70694 001
MAR 04, 1986

AMINOPHYLLINE (PAGE 3-10)

TABLET; ORAL

AMINOPHYLLINE
AB CORD LABORATORIES 100MG N85262 002
/BD/ /CORD LABORATORIES/ /100MG/ /N85262 002/

AMIODARONE HYDROCHLORIDE (PAGE 3-11)

TABLET; ORAL

CORDARONE
IVES LABS/AMNO 200MG¤ N18972 001
DEC 24, 1985

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE (PAGE 3-14)

TABLET; ORAL

LIMBITROL
/HOFFMANN-LA ROCHE /12.5MG;5MG/ /N16948 001/
/25MG;10MG/ /N16949 002/
EQ 12.5MG BASE;5MG N16949 001
EQ 25MG BASE;10MG N16949 002

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL
> ADD > AB BARR LABORATORIES 10MG;2MG¤ N71077 001
> ADD > NOV 12, 1986
> ADD > AB 25MG;2MG¤ N70297 001
> ADD > NOV 12, 1986
> ADD > AB 10MG;4MG¤ N71078 001
> ADD > NOV 12, 1986
> ADD > AB 25MG;4MG¤ N71079 001
> ADD > NOV 12, 1986

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

	AB	BOLAR PHARMACEUTICAL	10MG;2MG	N70373 001	AUG 25, 1986
	AB		25MG;2MG	N70374 001	AUG 25, 1986
	AB		10MG;4MG	N70375 001	AUG 25, 1986
	AB		25MG;4MG	N70376 001	AUG 25, 1986
> ADD >	AB		50MG;4MG	N70377 001	NOV 04, 1986
> ADD >	AB	CHELSEA LABORATORIES	10MG;2MG	N71384 001	NOV 03, 1986
> ADD >	AB		25MG;2MG	N71385 001	NOV 03, 1986
> ADD >	AB		10MG;4MG	N71386 001	NOV 03, 1986
> ADD >	AB		25MG;4MG	N71387 001	NOV 03, 1986
> ADD >	AB	PAR PHARMACEUTICAL	10MG;2MG	N70565 001	SEP 11, 1986
	AB		25MG;2MG	N70621 001	SEP 11, 1986
	AB		10MG;4MG	N70620 001	SEP 11, 1986
	AB		25MG;4MG	N70595 001	SEP 11, 1986
	AB		50MG;4MG	N70574 001	SEP 11, 1986
	AB	ZENITH LABORATORIES	10MG;2MG	N70935 001	SEP 11, 1986
	AB		25MG;2MG	N70936 001	SEP 11, 1986
	AB		10MG;4MG	N70937 001	SEP 11, 1986
	AB		25MG;4MG	N70938 001	SEP 11, 1986
	AB		50MG;4MG	N70939 001	SEP 12, 1986
		TRIAVIL 2-10			
	/BP/	/MS&D/MERCK/	/10MG;2MG/	/N14715 004/	
		TRIAVIL 2-25			
	/BP/	/MS&D/MERCK/	/25MG;2MG/	/N14715 002/	
		TRIAVIL 4-10			
	/BP/	/MS&D/MERCK/	/10MG;4MG/	/N14715 001/	
	/BP/	/MS&D/MERCK/	/10MG;4MG/	/N14715 003/	
		TRIAVIL 4-25			
	/BP/	/MS&D/MERCK/	/25MG;4MG/	/N14715 005/	
		TRIAVIL 4-50			
	/BP/	/MS&D/MERCK/	/50MG;4MG/	/N14715 006/	

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

TABLET; ORAL

TRIAVIL 2-10

AB	MS&D/MERCK	10MG;2MG	N14715 004

TRIAVIL 2-25

AB	MS&D/MERCK	25MG;2MG	N14715 002

TRIAVIL 4-10

AB	MS&D/MERCK	10MG;4MG	N14715 003

TRIAVIL 4-25

AB	MS&D/MERCK	25MG;4MG	N14715 005

TRIAVIL 4-50

AB	MS&D/MERCK	50MG;4MG	N14715 006

AMOXICILLIN (PAGE 3-15)

CAPSULE; ORAL

AMOXICILLIN

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

UTIMOX

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

POWDER FOR RECONSTITUTION; ORAL

UTIMOX

AB	PARKE-DAVIS/W-L	125MG/5ML	N62127 001
AB		250MG/5ML	N62127 002

AMPICILLIN SODIUM (PAGE 3-17)

INJECTABLE; INJECTION

AMPICILLIN SODIUM

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

TOTACILLIN-N

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

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

INJECTABLE; INJECTION

M.V.I.-12 LYOPHILIZED

	USV PHARMACEUTICAL	100MG/VIAL;0.06MG/VIAL;0.05MG/VIAL 15MG/VIAL;200 IU/VIAL;0.4MG/VIAL; 40MG/VIAL;4MG/VIAL;3.6MG/VIAL; 3MG/VIAL;3,300 IU/VIAL;10 IU/VIAL*		N18933 002 AUG 08, 1985

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

INJECTABLE; INJECTION

M.V.C. 9+3

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

M.V.I.-12

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

MVC PLUS

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

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

INJECTABLE; INJECTION

BEROCCA PN

	HOFFMANN-LA ROCHE	50MG/ML;0.03MG/ML;0.0025MG/ML; 7.5MG/ML;100 IU/ML;0.2MG/ML;20MG/ML; 2MG/ML;1.8MG/ML;1.5MG/ML;1,650 IU/ML; 5 IU/ML*		N06071 003 OCT 10, 1985

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)

CAPSULE; ORAL

BUTALBITAL W/ ASPIRIN AND CAFFEINE

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

FIORINAL

AB	SANDOZ PHARMS/SANDOZ	325MG;50MG;40MG*		N17534 005 APR 16, 1986

LANORINAL

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

TABLET; ORAL

BUTALBITAL W/ ASPIRIN AND CAFFEINE

AB	WEST-WARD	325MG;50MG;40MG		N86162 002 FEB 16, 1984

FIORINAL

AB	SANDOZ PHARMS/SANDOZ	325MG;50MG;40MG*		N17534 003 APR 16, 1986

LANORINAL

AB	LANNETT	325MG;50MG;40MG*		N86986 002 OCT 18, 1985

ASPIRIN; CARISOPRODOL (PAGE 3-20)

TABLET; ORAL

CARISOPRODOL COMPOUND

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

SOMA COMPOUND

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

ASPIRIN; MEPROBAMATE (PAGE 3-20)

TABLET; ORAL

MEPROBAMATE AND ASPIRIN

AB	PAR PHARMACEUTICAL	325MG;200MG*		N89126 001 AUG 19, 1986

ASPIRIN; METHOCARBAMOL (PAGE 3-20)

TABLET; ORAL

METHOCARBAMOL AND ASPIRIN

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

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE (PAGE 3-20)

TABLET; ORAL

DLT > /OXYCODONE HCL; ASPIRIN (FULL-STRENGTH)/
ADD > ROXIPRIN

AA	ROXANE LABORATORIES	325MG;4.5MG;0.38MG	N87743 001	JUN 04, 1982

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-23)

OINTMENT; TOPICAL

ARTISPORIN

AT	BURROUGHS WELLCOME	400 UNITS/GM;1%;EQ 3.5MG BASE/GM; 5,000 UNITS/GM	N50168 002	MAY 04, 1985

NEOMYCIN & POLYMYXIN B SULFATES & BACITRACIN ZINC & HYDROCORTISONE

AT	PHARMAFAIR	400 UNITS/GM;1%;EQ 3.5MG BASE/GM; 5,000 UNITS/GM‡	N62381 001	SEP 06, 1985

BENZYL PENICILLOYL-POLYLYSINE (PAGE 3-25)

INJECTABLE; INJECTION

PRE-PEN

/KREMERS-URBAN/	/60 UMOLAR/	/N50114 001/	
SCHWARZ PHARMS	60 UMOLAR	N50114 001	

BETAMETHASONE BENZOATE (PAGE 3-25)

CREAM; TOPICAL

/BENISONE/

/PARKE-DAVIS/W-L/	/0.025%/	/N16998 001/	

UTICORT

PARKE-DAVIS/W-L	0.025%	N16998 002	

GEL; TOPICAL

/BENISONE/
UTICORT

OINTMENT; TOPICAL

/BENISONE/
UTICORT

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

CREAM; TOPICAL

DIPROLENE

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

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

LOTION; TOPICAL

ALPHATREX

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

BETAMETHASONE DIPROPIONATE

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

BETAMETHASONE VALERATE (PAGE 3-26)

CREAM; TOPICAL

BETAMETHASONE VALERATE

AB	CLAY-PARK LABS	EQ 0.1% BASE‡	N70053 001	JUN 10, 1986

OINTMENT; TOPICAL

BETA-VAL

AB	FEMMON	EQ 0.1% BASE‡	N70069 001	DEC 19, 1985

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC

BETOPTIC

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

BETHANECHOL CHLORIDE (PAGE 3-27)

TABLET; ORAL

BETHANECHOL CHLORIDE

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

BRETYLIUM TOSYLATE (PAGE 3-28)

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

AP	ABBOTT LABORATORIES	50MG/ML‡	N19033 001	APR 29, 1986 : APR 16, 1986
AP	ELKINS-SINN/AHROBINS	50MG/ML‡	N70545 001	MAY 14, 1986
AP		50MG/ML‡	N70546 001	MAY 14, 1986

BRETYLIUM TOSYLATE (PAGE 3-28)

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

AP	INTL MEDICATION SYS	50MG/ML¤		N70119 001
			APR 29, 1986 :	MAR 06, 1986
AP	LYPHOMED	50MG/ML¤		N70134 001
			APR 29, 1986 :	FEB 12, 1986

BRETYLIUM TOSYLATE IN PLASTIC CONTAINER

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

BRETYLOL

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

BRETYLIUM TOSYLATE; DEXTROSE (PAGE 3-28)

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE IN DEXTROSE 5%

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

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

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

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-28)

SYRUP; ORAL

AMBENYL

/AA/	/MARION LABORATORIES/	/12.5MG/5ML;10MG/5ML/	/N09319 006/ /JAN 10, 1984/
AA	FOREST LABORATORIES	12.5MG/5ML;10MG/5ML	N09319 006 JAN 10, 1984

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-29)

/TABLET, CONTROLLED RELEASE; ORAL

/DINETAPP/

/AH ROBINS/	/12MG;75MG/	/N12436 002/ /APR 02, 1984/

BUPIVACAINE HYDROCHLORIDE (PAGE 3-29)

INJECTABLE; INJECTION

SENSORCAINE

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

BUPIVACAINE HYDROCHLORIDE; DEXTROSE (PAGE 3-29)

INJECTABLE; INJECTION

MARCAINE SPINAL

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

BUPROPION HYDROCHLORIDE (PAGE 3-30)

TABLET; ORAL

WELLBUTRIN

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

BUSPIRONE HYDROCHLORIDE (PAGE 3-30)

TABLET; ORAL

BUSPAR

	BRISTOL LABS/B-M	5MG¤	N18731 001 SEP 29, 1986
		10MG¤	N18731 002 SEP 29, 1986

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

~~CALCIFEDIOL, ANHYDROUS~~ (PAGE 3-31)
CALCIFEDIOL, ANHYDROUS (PAGE 3-31)

CALCITONIN, HUMAN (PAGE3-31)

INJECTABLE; INJECTION
CIBACALCIN
CIBA/CIBA-GEIGY 0.5MG/VIAL* N18470 001 OCT 31, 1986

CALCITONIN, SALMON (PAGE 3-31)

INJECTABLE; INJECTION
MIACALCIN
SANDOZ PHARMS/SANDOZ 100 IU/ML* N17808 001 JUL 03, 1986

CALCITROL (PAGE 3-31)

INJECTABLE; INJECTION
CALCIJEX
ABBOTT LABORATORIES 0.001MG/ML N18874 001 SEP 25, 1986
0.002MG/ML N18874 002 SEP 25, 1986

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 25MG/100ML;2.5GM/100ML; 15MG/100ML;610MG/100ML; 560MG/100ML* N18460 006 JAN 29, 1986

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

SOLUTION; INTRAPERITONEAL
DIALYTE W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
KENDALL MCGAW LABS 26MG/100ML;1.5GM/100ML; 5MG/100ML;530MG/100ML; 450MG/100ML* N18460 007 JAN 29, 1986
DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
KENDALL MCGAW LABS 26MG/100ML;2.5GM/100ML; 5MG/100ML;530MG/100ML; 450MG/100ML* N18460 008 JAN 29, 1986
DIALYTE W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
KENDALL MCGAW LABS 26MG/100ML;4.25GM/100ML; 5MG/100ML;530MG/100ML; 450MG/100ML* N18460 009 JAN 29, 1986
DIANEAL PD-1 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
TRAVENOL LABS 25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML* N17512 010 NOV 18, 1985
DIANEAL PD-2 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
TRAVENOL LABS 25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538/100ML; 448MG/100ML* N17512 011 NOV 18, 1985

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

SOLUTION; INTRAPERITONEAL
INPERSOL-ZM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 25.7MG/100ML;1.5GM/100ML; 538MG/100ML;448MG/100ML* N19395 001 MAR 26, 1986
INPERSOL-ZM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 25.7MG/100ML;2.5GM/100ML; 538MG/100ML;448MG/100ML* N19395 002 MAR 26, 1986
INPERSOL-ZM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 25.7MG/100ML;4.25GM/100ML; 538MG/100ML;448MG/100ML* N19395 003 MAR 26, 1986

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

INJECTABLE; INJECTION
TPN ELECTROLYTES IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	16.5MG/ML;25.4MG/ML;74.6MG/ML; 121MG/ML;16.1MG/ML‡	N19399 001	JUN 16, 1986
		16.5MG/ML;25.4MG/ML;74.6MG/ML; 121MG/ML;16.1MG/ML	N18895 001	JUL 20, 1984

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

INJECTABLE; INJECTION
LACTATED RINGER'S IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML‡	N19485 001	OCT 24, 1985

SOLUTION; IRRIGATION
LACTATED RINGER'S IN PLASTIC CONTAINER

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

CAPTOPRIL (PAGE 3-36)

TABLET; ORAL
CAPOTEN

	ER SQUIBB AND SONS	37.5MG‡	N18343 006	SEP 17, 1986

CARBACHOL (PAGE 3-36)

INJECTABLE; INJECTION
CARBACHOL

AP	PHARMAFAIR	0.01%‡	N70292 001	MAY 21, 1986

MIOSTAT

AP	ALCON LABORATORIES	0.01%	N16968 001	

CARBAMAZEPINE (PAGE 3-36)

TABLET; ORAL
CARBAMAZEPINE

AB	COLMED LABORATORIES	200MG‡	N70300 001	MAY 15, 1986
AB	INWOOD LABS/FOREST	200MG‡	N70231 001	AUG 14, 1986

CARBAMAZEPINE (PAGE 3-36)

TABLET; ORAL
EPITOL

AB	LEMMON	200MG‡	N70541 001	SEP 17, 1986

TEGRETOL

AB	GEIGY/CIBA-GEIGY	200MG	N16608 001	

CARNITINE, L- (PAGE 3-37)

SOLUTION; ORAL
VITACARN

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

TABLET; ORAL
/L-CARNITINE/
CARNITOR

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

CEFAMANDOLE NAFATE (PAGE 3-37)

INJECTABLE; INJECTION
MANDOL

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

CEFAZOLIN SODIUM (PAGE 3-38)

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

>ADD> AP	LYPHOMED	EQ 500MG BASE/VIAL‡	N62688 002	NOV 17, 1986
>ADD> AP		EQ 1GM BASE/VIAL‡	N62688 003	NOV 17, 1986
>ADD> AP		EQ 10GM BASE/VIAL‡	N62688 004	NOV 17, 1986

KEFZOL

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

CEFOPERAZONE SODIUM; DEXTROSE (PAGE 3-38)

INJECTABLE; INJECTION
CEFOBID IN PLASTIC CONTAINER

ROERIG/PFIZER	EQ 40MG BASE/ML;36MG/ML*	N50613 001	JUL 23, 1986

CEFOTETAN DISODIUM (PAGE 3-38)

INJECTABLE; INJECTION
CEFOTAN

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

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION
FORTAZ

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

TAZICEF

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

TAZIDIME

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

TAZIDIME IN PLASTIC CONTAINER

AP	ELI LILLY	1GM/VIAL*	N62739 001	JUL 10, 1986
AP		2GM/VIAL*	N62739 002	JUL 10, 1986

CEFUROXIME SODIUM (PAGE 3-40)

INJECTABLE; INJECTION
KEFUROX

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

KEFUROX IN PLASTIC CONTAINER

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

ZINACEF

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

CEPHALOTHIN SODIUM (PAGE 3-40)

INJECTABLE; INJECTION
CEPHALOTHIN SODIUM

AP	ABBOTT LABORATORIES	EQ 1GM BASE/VIAL*	N62547 001	SEP 11, 1985
AP		EQ 1GM BASE/VIAL*	N62548 001	SEP 11, 1985
AP		EQ 2GM BASE/VIAL*	N62547 002	SEP 11, 1985
AP		EQ 2GM BASE/VIAL*	N62548 002	SEP 11, 1985

KEFLIN IN PLASTIC CONTAINER

AP	ELI LILLY	EQ 1GM BASE/VIAL*	N62549 001	SEP 10, 1985
AP		EQ 2GM BASE/VIAL*	N62549 002	SEP 10, 1985

CEPHAPIRIN SODIUM (PAGE 3-41)

INJECTABLE; INJECTION
CEFADYL

>ADD> AP	BRISTOL LABS/B-M	EQ 500MG BASE/VIAL	N50446 005		
>ADD> AP		EQ 1GM BASE/VIAL	N50446 001		
>ADD> AP		EQ 1GM BASE/VIAL	N61769 001		
>ADD> AP		EQ 2GM BASE/VIAL	N50446 002		
>ADD> AP		EQ 2GM BASE/VIAL	N61769 002		
>ADD> AP		EQ 4GM BASE/VIAL	N50446 003		
>ADD> AP		EQ 20GM BASE/VIAL	N50446 004		

CEPHAPIRIN SODIUM (PAGE 3-41)

INJECTABLE; INJECTION
CEPHAPIRIN SODIUM

> ADD >	AP	LYPHOMED	EQ 500MG BASE/VIAL*	N62723 001 NOV 17, 1986
> ADD >	AP		EQ 1GM BASE/VIAL*	N62723 002 NOV 17, 1986
> ADD >	AP		EQ 2GM BASE/VIAL*	N62723 003 NOV 17, 1986
> ADD >	AP		EQ 4GM BASE/VIAL*	N62723 004 NOV 17, 1986
> ADD >	AP		EQ 20GM BASE/VIAL*	N62723 005 NOV 17, 1986

CHLORAMPHENICOL (PAGE 3-42)

SOLUTION/DROPS; OPHTHALMIC
CHLORAMPHENICOL

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

CHLORHEXIDINE GLUCONATE (PAGE 3-44)

SOLUTION; DENTAL
PERIDEX

	PROCTER AND GAMBLE	0.12%*	N19028 001 AUG 13, 1986

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-46)

CAPSULE, CONTROLLED RELEASE; ORAL
DRIZE

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

ORNADE

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

CHLORPROPAMIDE (PAGE 3-48)

TABLET; ORAL
CHLORPROPAMIDE

> ADD >	AB	BARR LABORATORIES	100MG*	N89446 001 NOV 17, 1986
> ADD >	AB		250MG*	N89447 001 NOV 17, 1986

CHLORPROPAMIDE (PAGE 3-48)

TABLET; ORAL
CHLORPROPAMIDE

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

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL
CHLORTHALIDONE

AB	MUTUAL PHARM	25MG*	N89285 001 JUL 21, 1986
AB		50MG*	N89286 001 JUL 21, 1986
AB	PUREPAC/KALIPHARMA	25MG*	N89139 001 JUL 16, 1986
AB	SIDMAK LABORATORIES	25MG*	N88902 001 SEP 19, 1985
AB		50MG*	N88903 001 SEP 19, 1985

CHROMIC CHLORIDE (PAGE 3-50)

INJECTABLE; INJECTION
CHROMIC CHLORIDE IN PLASTIC CONTAINER

ABBOTT LABORATORIES	EQ 0.004MG CHROMIUM/ML*	N18961 001 JUN 26, 1986

CHYMOPAPAIN (PAGE 3-50)

INJECTABLE; INJECTION
CHYMODIACTIN

/SMITH LABORATORIES/	/4,000 UNITS/VIAL/	/N18663 002/ /AUG 21, 1984/
	/10,000 UNITS/VIAL/	/N18663 001/ /NOV 10, 1982/
TRAVENOL LABS	4,000 UNITS/VIAL	N18663 002 AUG 21, 1984
	10,000 UNITS/VIAL	N18663 001 NOV 10, 1982

CILASTATIN SODIUM; IMIPENEM (PAGE 3-50)

INJECTABLE; INJECTION
PRIMAXIN
MS&D RES LABS/MERCK — EQ 250MG BASE/VIAL; 250MG/VIAL‡ — N50587 001 — NOV 26, 1985
EQ 500MG BASE/VIAL; 500MG/VIAL‡ — N50587 002 — NOV 26, 1985

CIMETIDINE (PAGE 3-50)

TABLET; ORAL
TAGAMET
SK&F LAB — 800MG‡ — N17920 005 — APR 30, 1986

CIMETIDINE HYDROCHLORIDE; SODIUM CHLORIDE (PAGE 3-50)

INJECTABLE; INJECTION
TAGAMET IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
SK&F LAB — EQ 6MG BASE/ML;9MG/ML‡ — N19434 001 — OCT 31, 1985

CLINDAMYCIN PALMITATE HYDROCHLORIDE (PAGE 3-51)

POWDER FOR RECONSTITUTION; ORAL
CLEOCIN
AA UPJOHN — EQ 75MG BASE/5ML‡ — N62644 001 — APR 07, 1986
AA UPJOHN MANUFACTURING — EQ 75MG BASE/5ML — N61827 001

CLOBETASOL PROPIONATE (PAGE 3-51)

CREAM; TOPICAL
TEMOVATE
GLAXO — 0.05%‡ — N19322 001 — DEC 27, 1985

OINTMENT; TOPICAL
TEMOVATE
GLAXO — 0.05%‡ — N19323 001 — DEC 27, 1985

CLOFIBRATE (PAGE 3-51)

CAPSULE; ORAL
ATROMID-S
AB AYERST LABS/AMHO — 500MG — N16099 002
CLOFIBRATE
AB FORMUTEC — 500MG‡ — N70531 001 — JUN 16, 1986

CLONAZEPAM (PAGE 3-52)

TABLET; ORAL
/CLONOPIN/
KLONOPIN
HOFFMANN-LA ROCHE — 0.5MG — N17533 001
1MG — N17533 002
2MG — N17533 003

CLONIDINE HYDROCHLORIDE (PAGE 3-52)

TABLET; ORAL
CATAPRES
AB BOEHRINGER INGELHEIM — 0.1MG — N17407 001
AB 0.2MG — N17407 002
AB 0.3MG — N17407 003
CLONIDINE HCL
AB AM THERAPEUTICS — 0.1MG‡ — N70881 001 — JUL 08, 1986 : MAY 27, 1986
AB 0.2MG‡ — N70882 001 — JUL 08, 1986 : MAY 27, 1986
AB 0.3MG‡ — N70883 001 — JUL 08, 1986 : MAY 27, 1986
AB BIOCRAFT LABS — 0.1MG‡ — N70747 001 — JUL 08, 1986 : MAR 20, 1986
AB 0.2MG‡ — N70702 001 — JUL 08, 1986 : MAR 20, 1986
AB 0.3MG‡ — N70659 001 — JUL 08, 1986 : MAR 20, 1986
AB DANBURY PHARMACAL — 0.1MG‡ — N70965 001 — JUL 08, 1986 : JUL 01, 1986
AB 0.2MG‡ — N70964 001 — JUL 08, 1986 : JUL 01, 1986
AB 0.3MG‡ — N70963 001 — JUL 08, 1986 : JUL 01, 1986
AB DURAMED PHARMS — 0.1MG‡ — N71103 001 — AUG 14, 1986
AB 0.2MG‡ — N71102 001 — AUG 14, 1986
AB 0.3MG‡ — N71101 001 — AUG 14, 1986
AB INTERPHARM — 0.1MG‡ — N71252 001 — OCT 01, 1986
AB 0.2MG‡ — N71253 001 — OCT 01, 1986
AB 0.3MG‡ — N71254 001 — OCT 01, 1986
AB PAR PHARMACEUTICAL — 0.1MG‡ — N70461 001 — JUL 08, 1986 : NOV 22, 1985
AB 0.2MG‡ — N70460 001 — JUL 08, 1986 : NOV 22, 1985
AB 0.3MG‡ — N70459 001 — JUL 08, 1986 : NOV 22, 1985

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

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

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-53)

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

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-53)

SYRUP; ORAL
HISTAFED C
AA LIFE LABORATORIES 10MG/5ML;30MG/5ML; 1.25MG/5ML℠ N89018 001 JUL 23, 1986

COPPER (PAGE 3-54)

INTRAUTERINE DEVICE; INTRAUTERINE
CU-7
∂ SEARLE PHARMS 89MG N17408 001
TATUM-T
∂ SEARLE PHARMS 120MG N18205 001

CROMOLYN SODIUM (PAGE 3-55)

AEROSOL; INHALATION
INTAL
FISONS 0.8MG/INH℠ N18887 001 DEC 05, 1985

CUPRIC CHLORIDE (PAGE 3-55)

INJECTABLE; INJECTION
CUPRIC CHLORIDE IN PLASTIC CONTAINER
ABBOTT LABORATORIES EQ 0.4MG COPPER/ML℠ N18960 001 JUN 26, 1986

CYCLOPHOSPHAMIDE (PAGE 3-57)

INJECTABLE; INJECTION
CYCLOPHOSPHAMIDE
AP ELKINS-SINN/AHROBINS 100MG/VIAL℠ N88371 001 JUL 03, 1986
AP 200MG/VIAL℠ N88372 001 JUL 03, 1986
AP 500MG/VIAL℠ N88373 001 JUL 03, 1986
AP 1GM/VIAL℠ N88374 001 SEP 24, 1986 : JUL 03, 1986
CYTOXAN
AP BRISTOL LABS/B-M 2GM/VIAL N12142 005 AUG 30, 1982
LYOPHILIZED CYCLOPHOSPHAMIDE
AP LYPHOMED 100MG/VIAL℠ N89194 001 AUG 27, 2002 : JUL 07, 1986
AP 200MG/VIAL℠ N89195 001 AUG 27, 2002 : JUL 07, 1986
AP 500MG/VIAL℠ N89196 001 AUG 27, 2002 : JUL 07, 1986
LYOPHILIZED CYTOXAN
AP BRISTOL LABS/B-M 100MG/VIAL℠ N12142 006 DEC 05, 1985
AP 200MG/VIAL℠ N12142 007 DEC 10, 1985
AP 500MG/VIAL℠ N12142 008 JAN 04, 1984
AP 1GM/VIAL℠ N12142 010 SEP 24, 1985
AP 2GM/VIAL℠ N12142 009 DEC 10, 1984

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-58)

SYRUP; ORAL
CYPROHEPTADINE HCL
AA HALSEY DRUG 2MG/5ML℠ N89199 001 JUL 03, 1986

TABLET; ORAL
CYPROHEPTADINE HCL
AA HALSEY DRUG 4MG℠ N89057 001 JUL 03, 1986

CYSTEINE HYDROCHLORIDE (PAGE 3-58)

INJECTABLE; INJECTION
CYSTEINE HCL
KABIVITRUM 7.25%℠ N19523 001 OCT 22, 1986

DACARBAZINE (PAGE 3-58)

INJECTABLE; INJECTION

DACARBAZINE

AP	LYPHOMED	100MG/VIAL¤	N70962 001	AUG 28, 1986
AP		200MG/VIAL¤	N70990 001	AUG 28, 1986
AP	QUAD PHARMS	100MG/VIAL¤	N70821 001	OCT 09, 1986
AP		200MG/VIAL¤	N70822 001	OCT 09, 1986

DTIC-DOME

AP	MILES PHARMS/MILES	100MG/VIAL	N17575 001	
AP		200MG/VIAL	N17575 002	

DEXAMETHASONE (PAGE 3-60)

ELIXIR; ORAL

DEXAMETHASONE

AA	NASKA PHARMACAL	0.5MG/5ML¤	N88997 001	OCT 10, 1986

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-62)

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

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

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE (PAGE 3-63)

SOLUTION/DROPS; OPHTHALMIC

NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

AT	CARTER-GLOGAU LABS	EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML¤	N62714 001	JUL 21, 1986

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-62)

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

>ADD>					
>ADD>	AT	CARTER-GLOGAU LABS	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML¤	N62721 001	NOV 17, 1986
>ADD>					

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)

TABLET; ORAL

DEXCHLORPHENIRAMINE MALEATE

AA	SIDMAK LABORATORIES	2MG¤	N88682 001	JAN 17, 1986

POLARAMINE

AA	SCHERING	2MG	N86835 001	

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION

DEXTROSE 5% IN PLASTIC CONTAINER

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

DEXTROSE 50% IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	500MG/ML¤	N19445 001	JUN 03, 1986

DEXTROSE; DOPAMINE HYDROCHLORIDE (PAGE 3-65)

INJECTABLE; INJECTION

DOPAMINE HCL IN DEXTROSE 5%

	KENDALL MCGAW LABS	5GM/100ML;40MG/100ML¤	N19099 001	OCT 15, 1986
AP		5GM/100ML;80MG/100ML¤	N19099 002	OCT 15, 1986
AP		5GM/100ML;160MG/100ML¤	N19099 003	OCT 15, 1986
AP		5GM/100ML;320MG/100ML¤	190990 004	OCT 15, 1986

DOPAMINE HCL IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	5GM/100ML;320MG/100ML	N18826 003	SEP 30, 1983

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION

LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

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

INJECTABLE; INJECTION
IONOSOL B AND DEXTROSE 5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5GM/100ML;53MG/100ML;100MG/100ML; 100MG/100ML;180MG/100ML; 280MG/100ML;16MG/100ML¤ N19515 001 MAY 08, 1986

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

INJECTABLE; INJECTION
IONOSOL MB AND DEXTROSE 5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5GM/100ML;30MG/100ML;141MG/100ML; 15MG/100ML;260MG/100ML; 25MG/100ML¤ N19513 001 MAY 08, 1986

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

INJECTABLE; INJECTION
IONOSOL T AND DEXTROSE 5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5GM/100ML;111MG/100ML;256MG/100ML; 146MG/100ML;207MG/100ML¤ N19514 001 MAY 08, 1986

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

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

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

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

DEXTROSE; 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

AP	CARTER-GLOGAU LABS	5MG/ML*	N70296 001 FEB 12, 1986
AP	ELKINS-SINN/AHROBINS	5MG/ML*	N70311 001 DEC 16, 1985
AP		5MG/ML*	N70312 001 DEC 16, 1985
AP		5MG/ML*	N70313 001 DEC 16, 1985
AP	LEMMON	5MG/ML*	N70911 001 AUG 28, 1986
AP		5MG/ML*	N70912 001 AUG 28, 1986
AP	LYPHOMED	5MG/ML*	N70662 001 JUN 25, 1986

VALIUM

AP	HOFFMANN-LA ROCHE	5MG/ML	N16087 001

TABLET; ORAL

DIAZEPAM

AB	BARR LABORATORIES	2MG*	N70152 001 NOV 01, 1985
AB		5MG*	N70153 001 NOV 01, 1985
AB		10MG*	N70154 001 NOV 01, 1985
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	DURAMED PHARMS	2MG*	N70894 001 AUG 27, 1986
AB		5MG*	N70895 001 AUG 27, 1986
AB		10MG*	N70896 001 AUG 27, 1986
AB	HALSEY DRUG	2MG*	N70987 001 AUG 15, 1986
AB		5MG*	N70996 001 AUG 15, 1986
AB		10MG*	N70956 001 AUG 15, 1986

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

DIAZEPAM

AB	LEDERLE LABS/AM CYAN	2MG*	N70226 001 SEP 26, 1985
AB		5MG*	N70227 001 SEP 26, 1985
AB		10MG*	N70228 001 SEP 26, 1985
AB	MYLAN PHARMS	2MG*	N70323 001 SEP 04, 1985
AB		5MG*	N70324 001 SEP 04, 1985
AB		10MG*	N70325 001 SEP 04, 1985
AB	PAR PHARMACEUTICAL	2MG*	N70462 001 FEB 25, 1986
AB		5MG*	N70463 001 FEB 25, 1986
AB		10MG*	N70464 001 FEB 25, 1986
AB	PARKE-DAVIS/W-L	2MG*	N70209 001 SEP 04, 1985
AB		5MG*	N70210 001 SEP 04, 1985
AB		10MG*	N70222 001 SEP 04, 1985
AB	PUREPAC/KALIPHARMA	2MG*	N70781 001 MAR 19, 1986
AB		5MG*	N70706 001 MAR 19, 1986
AB		10MG*	N70707 001 MAR 19, 1986
AB	ROXANE LABORATORIES	2MG*	N70356 001 JUN 17, 1986
AB		5MG*	N70357 001 JUN 17, 1986
AB		10MG*	N70358 001 JUN 17, 1986
AB	SUPERPHARM	2MG*	N70642 001 DEC 11, 1985
AB		5MG*	N70643 001 DEC 11, 1985
AB		10MG*	N70644 001 DEC 11, 1985
AB	ZENITH LABORATORIES	2MG*	N70360 001 SEP 04, 1985
AB		5MG*	N70361 001 SEP 04, 1985
AB		10MG*	N70362 001 SEP 04, 1985

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

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

DICYCLOMINE HYDROCHLORIDE (PAGE 3-73)

CAPSULE; ORAL

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

INJECTABLE; INJECTION

	BENTYL			
AP	MERRELL DON/DON CHEM	10MG/ML	N08370 001	OCT 15, 1984
	DICYCLOMINE HCL			
AP	CARTER-GLOGAU LABS	10MG/ML¤	N80614 001	FEB 11, 1986

TABLET; ORAL

	BENTYL			
AB	MERRELL DON/DON CHEM	20MG	N07409 001	OCT 15, 1984
	DICYCLOMINE HCL			
AB	BARR LABORATORIES	20MG	N84600 001	JUL 29, 1985
AB	BOLAR PHARMACEUTICAL	20MG¤	N84361 001	FEB 06, 1986
AB	PIONEER PHARMS	20MG¤	N88585 001	AUG 20, 1986

DIFLORASONE DIACETATE (PAGE 3-74)

CREAM; TOPICAL

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

OINTMENT; TOPICAL

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

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-76)

CAPSULE; ORAL

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

DISOPYRAMIDE PHOSPHATE (PAGE 3-77)

CAPSULE; ORAL

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

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION

DOPAMINE HCL

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

DOPASTAT

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

INTROPIN

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

DOXEPIN HYDROCHLORIDE (PAGE 3-78)

CAPSULE; ORAL

DOXEPIN HCL

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

DOXEPIN HYDROCHLORIDE (PAGE 3-78)

CAPSULE; ORAL

DOXEPIN HCL

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

DOXYCYCLINE HYCLATE (PAGE 3-79)

CAPSULE, COATED PELLETS; ORAL

DORYX

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

CAPSULE; ORAL

/DORYX/

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

DOXYCYCLINE HYCLATE

AB	MUTUAL PHARM	EQ 50MG BASE*	N62675 001	JUL 10, 1986
AB		EQ 100MG BASE*	N62676 001	JUL 10, 1986
AB	PARKE-DAVIS/W-L	EQ 50MG BASE*	N62594 001	DEC 05, 1985
AB		EQ 100MG BASE*	N62594 002	DEC 05, 1985
AB	PRIVATE FORMULATIONS	EQ 50MG BASE*	N62631 001	JUL 24, 1986
AB		EQ 100MG BASE*	N62631 002	JUL 24, 1986

INJECTABLE; INJECTION

/DOXYCYCLINE/

/AB/	/MEDICOPHARMA/	/EQ 100MG BASE*/	/N62536 001/	/APR 07, 1986/

DOXYCYCLINE HYCLATE

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

DOXYCYCLINE HYCLATE (PAGE 3-79)

TABLET; ORAL
DOXYCYCLINE HYCLATE

AB	MEDICOPHARMA	EQ 100MG BASE‡	N62538 001	APR 07, 1986
AB	MUTUAL PHARM	EQ 100MG BASE‡	N62677 001	JUL 10, 1986
AB	PARKE-DAVIS/W-L	EQ 100MG BASE‡	N62593 001	AUG 28, 1985
/AB/		/EQ 50MG BASE‡/	/N62594 001/	/DEC 05, 1985/
/AB/		/EQ 100MG BASE‡/	/N62594 002/	/DEC 05, 1985/

DOXYLAMINE SUCCINATE (PAGE 3-80)

TABLET; ORAL
DOXYLAMINE SUCCINATE

AA	COPLEY PHARM	25MG‡	N88900 001	OCT 08, 1985

DROPERIDOL (PAGE 3-80)

INJECTABLE; INJECTION
DROPERIDOL

>ADD> AP	LYPHOMED	2.5MG/ML‡	N70993 001	NOV 17, 1986
>ADD> AP		2.5MG/ML‡	N70992 001	NOV 17, 1986

INAPSINE

>ADD> AP	JANSSEN PHARMA	2.5MG/ML	N16796 001	

EDROPHONIUM CHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION
ENLON

AP	ANAQUEST/BOC	10MG/ML‡	N88873 001	AUG 06, 1985

TENSILON

AP	HOFFMANN-LA ROCHE	10MG/ML	N07959 001	

ENALAPRIL MALEATE (PAGE 3-81)

TABLET; ORAL
VASOTEC

MS&D RES LABS/MERCK	5MG‡	N18998 001	DEC 24, 1985
	10MG‡	N18998 002	DEC 24, 1985
	20MG‡	N18998 003	DEC 24, 1985

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE (PAGE 3-81)

TABLET; ORAL
VASERETIC

MS&D RES LABS/MERCK	10MG;25MG‡	N19221 001	OCT 31, 1986

EPINEPHRINE (PAGE 3-81)

INJECTABLE; INJECTION
SUS-PHRINE

/BERLEX/SCHERING/	/5MG/ML/	/N07942 001/	
FOREST LABORATORIES	5MG/ML	N07942 001	

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION
LIDOCAINE HCL AND EPINEPHRINE

AP	ABBOTT LABORATORIES	0.005MG/ML;1.5%‡	N88571 001	SEP 13, 1985

XYLOCAINE W/ EPINEPHRINE

AP	ASTRA PHARM PRODS	0.005MG/ML;1.5%	N10418 010	
AP		0.005MG/ML;1.5%	N06488 017	AUG 29, 1986

ERGOLOID MESYLATES (PAGE 3-82)

TABLET; ORAL
ERGOLOID MESYLATES

AB	BARR LABORATORIES	1MG‡	N88891 001	NOV 01, 1985

TABLET; SUBLINGUAL
ERGOLOID MESYLATES

AA	SUPERPHARM	0.5MG‡	N89233 001	SEP 23, 1986
AA		1MG‡	N89234 001	SEP 23, 1986

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

ERYTHROMYCIN (PAGE 3-83)

> ADD > POWDER; FOR RX COMPOUNDING
> ADD > ERYTHROMYCIN
> ADD > PADDOCK LABORATORIES 100%‡ N50610 001
> ADD > NOV 07, 1986

> DLT > /TABLET, ENTERIC-COATED PARTICLES, ORAL/
> ADD > TABLET, COATED PARTICLES; ORAL
PCE
ABBOTT LABORATORIES 333MG‡ N50611 001
SEP 09, 1986

ERYTHROMYCIN LACTOBIONATE (PAGE 3-85)

INJECTABLE; INJECTION
ERYTHROCIN LACTOBIONATE

AP	ABBOTT LABORATORIES	EQ 500MG BASE/VIAL‡	N50609 001	SEP 24, 1986
AP		EQ 1GM BASE/VIAL‡	N50609 002	SEP 24, 1986
AP		EQ 500MG BASE/VIAL‡	N62638 001	OCT 31, 1986
AP		EQ 1GM BASE/VIAL‡	N62638 002	OCT 31, 1986
> ADD > AP	LYPHOMED	EQ 500MG BASE/VIAL‡	N62604 001	NOV 24, 1986
> ADD > AP		EQ 1GM BASE/VIAL‡	N62604 002	NOV 24, 1986
> ADD > AP	QUAD PHARMS	EQ 500MG BASE/VIAL‡	N62660 001	NOV 24, 1986
> ADD > AP		EQ 1GM BASE/VIAL‡	N62660 003	NOV 24, 1986

ESTRADIOL (PAGE 3-86)

FILM, CONTROLLED RELEASE; PERCUTANEOUS
ESTRADERM

CIBA/CIBA-GEIGY	4MG‡	N19081 002	SEP 10, 1986
	8MG‡	N19081 003	SEP 10, 1986

ESTRADIOL CYPIONATE; TESTOSTERONE CYPIONATE (PAGE 3-86)

INJECTABLE; INJECTION
DEPO-TESTADIOL

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

TESTOSTERONE CYPIONATE-ESTRADIOL CYPIONATE

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

ESTROGEN, CONJUGATED (PAGE 3-86)

TABLET; ORAL
CONJUGATED ESTROGENS

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

ESTROGEN, CONJUGATED; MEPROBAMATE (PAGE 3-87)

TABLET; ORAL
PMB 200

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

PMB 400

/BS/	/AYERST LABS/AMHO/	/0.4MG;400MG/	/N10971 003/
BS	AYERST LABS/AMHO	0.45MG;400MG	N10971 003

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 3-89)

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

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

ETHINYL ESTRADIOL; NORETHINDRONE; FERROUS FUMARATE (PAGE 3-89)

TABLET; ORAL-28
NORQUEST FE
SYNTEX (FP) 0.035MG;1MG;75MG N18926 001
JUL 18, 1986

ETHOXZOLAMIDE (PAGE 3-90)

TABLET; ORAL
ETHAMIDE
@ ALLERGAN PHARMS 125MG N16144 001

ETRETINATE (PAGE 3-91)

CAPSULE; ORAL
TEGISON
HOFFMANN-LA ROCHE 10MG¤ N19369 001
SEP 30, 1986
25MG¤ N19369 002
SEP 30, 1986

FAMOTIDINE (PAGE 3-91)

> ADD > INJECTABLE; INJECTION
> ADD > PEPCID
> ADD > MSD RES LABS 10MG/ML¤ N19510 001
> ADD > NOV 04, 1986

TABLET; ORAL
PEPCID
MSD RES LABS 20MG¤ N19462 001
OCT 15, 1986
40MG¤ N19462 002
OCT 15, 1986

FLECAINIDE ACETATE (PAGE 3-92)

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

FLUNISOLIDE (PAGE 3-92)

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

AEROBID
KEY PHARMACEUTICALS 0.025MG/INH N18340 001
AUG 17, 1984

FLUOCINOLONE ACETONIDE (PAGE 3-92)

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

FLUOROMETHOLONE (PAGE 3-93)

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

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

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

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

FLUOROMETHOLONE ACETATE (PAGE 3-93)

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

FLUOROURACIL (PAGE 3-93)

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

FLUPHENAZINE DECANOATE (PAGE 3-94)

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

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

FLUPHENAZINE HYDROCHLORIDE (PAGE 3-94)

CONCENTRATE; ORAL

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

FLURAZEPAM HYDROCHLORIDE (PAGE 3-95)

CAPSULE; ORAL

	DALMANE			
AB	ROCHE PRODUCTS	15MG		N16721 001
AB		30MG		N16721 002
	FLURAZEPAM HCL			
AB	BARR LABORATORIES	15MG¤		N70454 001 AUG 04, 1986
AB		30MG¤		N70455 001 AUG 04, 1986
> ADD > AB	DANBURY PHARMACAL	15MG¤	> ADD >	N71205 001 NOV 25, 1986
> ADD > AB		30MG¤	> ADD >	N71068 001 NOV 25, 1986
AB	MYLAN PHARMS	15MG¤		N70344 001 NOV 27, 1985
AB		30MG¤		N70345 001 NOV 27, 1985
AB	PAR PHARMACEUTICAL	15MG¤		N70444 001 MAR 20, 1986
AB		30MG¤		N70445 001 MAR 20, 1986

/FOLATE SODIUM/(PAGE 3-95)

/INJECTABLE; INJECTION/

	/FOLVITE/			
	/LEDERLE LABS/AM CYAN/5MG BASE/ML/			/N05897 008/

FOLIC ACID (PAGE 3-95)

INJECTABLE; INJECTION

	FOLIC ACID			
AP	LYPHOMED	5MG/ML¤		N89202 001 FEB 18, 1986
	FOLVITE			
AP	LEDERLE LABS/AM CYAN	5MG/ML		N05897 008

FOLIC ACID (PAGE 3-95)

TABLET; ORAL

	FOLIC ACID			
AA	BARR LABORATORIES	1MG¤		N89177 001 JAN 08, 1986
AA	PIONEER PHARMS	1MG¤		N88949 001 SEP 13, 1985

FUROSEMIDE (PAGE 3-96)

INJECTABLE; INJECTION

	FUROSEMIDE			
AP	ASTRA PHARM PRODS	10MG/ML¤		N70014 001 SEP 09, 1985
AP		10MG/ML¤		N70095 001 SEP 09, 1985
AP		10MG/ML¤		N70096 001 SEP 09, 1985
AP	CARTER-GLOGAU LABS	10MG/ML¤		N70019 001 SEP 22, 1986
AP	SOLOPAK LABORATORIES	10MG/ML¤		N70023 001 FEB 05, 1986
AP		10MG/ML¤		N70078 001 FEB 05, 1986

TABLET; ORAL

	FUROSEMIDE			
AB	BARR LABORATORIES	20MG¤		N70043 001 SEP 26, 1985
AB	DANBURY PHARMACAL	20MG¤		N70412 001 FEB 26, 1986
AB		40MG¤		N70413 001 FEB 26, 1986
AB	MYLAN PHARMS	80MG¤		N70082 001 OCT 29, 1986
AB	ROXANE LABORATORIES	80MG¤		N70086 001 JAN 24, 1986
AB	WATSON LABORATORIES	20MG¤		N70449 001 NOV 22, 1985
AB		40MG¤		N70450 001 NOV 22, 1985
AB		80MG¤		N70528 001 JAN 07, 1986

GENTAMICIN SULFATE (PAGE 3-97)

INJECTABLE; INJECTION

	GENTAFAIR			
AP	PHARMAFAIR	EQ 40MG BASE/ML¤		N62493 001 AUG 28, 1985
	GENTAMICIN SULFATE			
AP	ABBOTT LABORATORIES	EQ 10MG BASE/ML¤		N62612 004 FEB 20, 1986

GENTAMICIN SULFATE (PAGE 3-97)

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

AT	CARTER-GLOGAU LABS	EQ 3MG BASE/ML‡	N62523 001	NOV 25, 1985

GENTAMICIN SULFATE; SODIUM CHLORIDE (PAGE 3-98)

INJECTABLE; INJECTION
GENTAMICIN SULFATE IN PLASTIC CONTAINER

AP	ABBOTT LABORATORIES	EQ 60MG BASE/100ML; 900MG/100ML‡	N62588 006	JAN 06, 1986
AP		EQ 70MG BASE/100ML; 900MG/100ML‡	N62588 007	JAN 06, 1986
AP		EQ 80MG BASE/100ML; 900MG/100ML‡	N62588 008	JAN 06, 1986
AP		EQ 90MG BASE/100ML; 900MG/100ML‡	N62588 009	JAN 06, 1986
AP		EQ 100MG BASE/100ML; 900MG/100ML‡	N62588 010	JAN 06, 1986
AP		EQ 1.2MG BASE/ML;9MG/ML‡	N62588 001	JAN 06, 1986
AP		EQ 1.4MG BASE/ML;9MG/ML‡	N62588 002	JAN 06, 1986
AP		EQ 1.6MG BASE/ML;9MG/ML‡	N62588 003	JAN 06, 1986
AP		EQ 1.8MG BASE/ML;9MG/ML‡	N62588 004	JAN 06, 1986
AP		EQ 2MG BASE/ML;9MG/ML‡	N62588 005	JAN 06, 1986

GLUTETHIMIDE (PAGE 3-100)

TABLET; ORAL
GLUTETHIMIDE

AA	HALSEY DRUG	250MG‡	N89458 001	OCT 10, 1986
AA		500MG‡	N89459 001	OCT 10, 1986

GLYCINE (PAGE 3-100)

SOLUTION; IRRIGATION
AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER

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

GLYCINE 1.5% IN PLASTIC CONTAINER

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

GLYCOPYRROLATE (PAGE 3-100)

INJECTABLE; INJECTION
GLYCOPYRROLATE

AP	LUITPOLD PHARMS	0.2MG/ML‡	N89335 001	JUL 23, 1986

GUANABENZ ACETATE (PAGE 3-102)

TABLET; ORAL
WYTENSIN

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

GUANFACINE HYDROCHLORIDE (PAGE 3-102)

TABLET; ORAL
TENEX

	AH ROBINS	1MG‡	N19032 001	OCT 27, 1986

HALOPERIDOL (PAGE 3-102)

TABLET; ORAL
HALDOL

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

HALOPERIDOL

>ADD> AB	CORD LABORATORIES	0.5MG‡	N71206 001	NOV 17, 1986
>ADD> AB		1MG‡	N71207 001	NOV 17, 1986
>ADD> AB		2MG‡	N71208 001	NOV 17, 1986
>ADD> AB		5MG‡	N71209 001	NOV 17, 1986

HALOPERIDOL (PAGE 3-102)

TABLET; ORAL
HALOPERIDOL

	AB	MYLAN PHARMS	0.5MG¤		N70276 001 JUN 10, 1986
	AB		1MG¤		N70277 001 JUN 10, 1986
	AB		2MG¤		N70278 001 JUN 10, 1986
	AB		5MG¤		N70279 001 JUN 10, 1986
> ADD >	AB	PAR PHARMACEUTICAL	0.5MG¤		N71233 001 NOV 03, 1986
> ADD >	AB		1MG¤		N71234 001 NOV 03, 1986
> ADD >	AB		2MG¤		N71235 001 NOV 03, 1986
> ADD >	AB		5MG¤		N71236 001 NOV 03, 1986
> ADD >	AB	PUREPAC/KALIPHARMA	0.5MG¤		N71071 001 NOV 03, 1986
> ADD >	AB		1MG¤		N71072 001 NOV 03, 1986
> ADD >	AB		2MG¤		N71073 001 NOV 03, 1986
> ADD >	AB		5MG¤		N71074 001 NOV 03, 1986
	AB	SEARLE PHARMS	0.5MG¤		N70720 001 JUN 10, 1986
	AB		1MG¤		N70721 001 JUN 10, 1986
	AB		2MG¤		N70722 001 JUN 10, 1986
	AB		5MG¤		N70723 001 JUN 10, 1986
	AB		10MG¤		N70724 001 JUN 10, 1986
	AB		20MG¤	SEP 24, 1986 :	JUN 10, 1986

HALOPERIDOL DECANOATE (PAGE 3-102)

INJECTABLE; INJECTION
HALDOL DECANOATE

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

HALOPERIDOL LACTATE (PAGE 3-102)

CONCENTRATE; ORAL
HALDOL

AA	MCNEIL LABORATORIES	EQ 2MG BASE/ML		N15922 001

HALOPERIDOL

AA	BAY LABORATORIES	EQ 2MG BASE/ML¤	APR 15, 1986 :	MAR 07, 1986
AA	NATL PHARM MFG/BARRE	EQ 2MG BASE/ML¤	APR 15, 1986 :	N70318 001 APR 11, 1986
AA	SEARLE PHARMS	EQ 2MG BASE/ML¤		N70726 001 JUN 10, 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	ABBOTT LABORATORIES	2,000 UNITS/ML¤		N05264 013 APR 07, 1986
AP		2,500 UNITS/ML¤		N05264 014 APR 07, 1986
AP	CARTER-GLOGAU LABS	100 UNIT/ML		N17064 001
AP		2,500 UNITS/ML		N17064 015
AP		7,500 UNITS/ML		N17064 019
		3,000 UNITS/ML		N17064 016
		4,000 UNITS/ML		N17064 017
		6,000 UNTIS/ML		N17064 018
AP	ELKINS-SINN/AHROBINS	5,000 UNITS/0.5ML¤		N17037 013 APR 07, 1986

HEPARIN SODIUM PRESERVATIVE FREE

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

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION

LIQUAEMIN SODIUM PRESERVATIVE FREE

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

SODIUM HEPARIN

/AP/	/CARTER-GLOBAL LABS/	/1,000 UNITS/ML/	/N17064 015/
/AP/		/2,500 UNITS/ML/	/N17064 019/
		/3,000 UNITS/ML/	/N17064 016/
		/4,000 UNITS/ML/	/N17064 017/
		/6,000 UNITS/ML/	/N17064 018/

HEXACHLOROPHENE (PAGE 3-106)

SPONGE; TOPICAL

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

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

INJECTABLE; INJECTION

HYDRALAZINE HCL

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

TABLET; ORAL

HYDRALAZINE HCL

AA	HALSEY DRUG	10MG*	N89218 001 JAN 22, 1986
AA		25MG*	N89130 001 JAN 15, 1986
AA		50MG*	N89222 001 JAN 22, 1986
AA		100MG*	N89178 001 JAN 15, 1986
AA	MUTUAL PHARM	10MG*	N89359 001 JUL 25, 1986
AA		25MG*	N89258 001 MAY 05, 1986
AA		50MG*	N89259 001 MAY 05, 1986
AA	SIDMAK LABORATORIES	10MG*	N89097 001 DEC 18, 1985
AA		100MG*	N89098 001 DEC 18, 1985

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-108)

CAPSULE; ORAL

HYDRA-ZIDE

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

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)

TABLET; ORAL

ALDORIL D30

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

ALDORIL D50

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

ALDORIL 15

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

ALDORIL 25

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

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	BOLAR PHARMACEUTICAL	15MG;250MG*	N70365 001 MAR 19, 1986
AB		25MG;250MG*	N70366 001 APR 16, 1986
AB		30MG;500MG*	N70367 001 MAR 19, 1986
AB		50MG;500MG*	N70368 001 APR 16, 1986
AB	CORD LABORATORIES	15MG;250MG*	N70182 001 JAN 15, 1986
AB		25MG;250MG*	N70183 001 JAN 15, 1986
AB		30MG;500MG*	N70543 001 JAN 15, 1986
AB		50MG;500MG*	N70544 001 JAN 15, 1986
AB	MYLAN PHARMS	15MG;250MG*	N70264 001 JAN 23, 1986
AB		25MG;250MG*	N70265 001 JAN 23, 1986
AB	PUREPAC/KALIPHARMA	15MG;250MG*	N70853 001 OCT 08, 1986
AB		25MG;250MG*	N70688 001 APR 24, 1986
AB		30MG;500MG*	N70854 001 OCT 08, 1986
AB		50MG;500MG*	N70689 001 APR 24, 1986

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE (PAGE 3-111)

TABLET; ORAL

	INDERIDE-40/25			
AB	AYERST LABS/AMHO	25MG;40MG	N18031 001	
	INDERIDE-80/25			
AB	AYERST LABS/AMHO	25MG;80MG	N18031 002	
	PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE			
AB	BARR LABORATORIES	25MG;40MG‡	N70704 001	OCT 01, 1986
AB		25MG;80MG‡	N70705 001	OCT 01, 1986
AB	CHELSEA LABORATORIES	25MG;40MG‡	N70301 001	APR 18, 1986
AB		25MG;80MG‡	N70305 001	APR 18, 1986
AB	PUREPAC/KALIPHARMA	25MG;40MG‡	N70851 001	MAY 15, 1986
AB		25MG;80MG‡	N70852 001	MAY 15, 1986

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL

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

/HYDROCODONE; PHENYLTOLOXAMINE/(PAGE 3-112)

/SUSPENSION; ORAL/

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

HYDROCORTISONE (PAGE 3-112)

CREAM; TOPICAL

	ALA-CORT			
AT	DEL-RAY LABORATORIES	1%	N80706 001	
	HYDROCORTISONE			
AT	PHARMADERM/ALTANA	1%‡	N88845 001	FEB 27, 1986

HYDROCORTISONE (PAGE 3-112)

LOTION; TOPICAL

	ALA-CORT			
AT	DEL-RAY LABORATORIES	1%	N83201 001	
	ALA-SCALP			
	DEL-RAY LABORATORIES	2%	N83231 001	
	HYDROCORTISONE			
AT	THAMES PHARMACAL	1%‡	N89024 001	FEB 12, 1986
	STIE-CORT			
AT	STIEFEL LABORATORIES	1%‡	N89066 001	NOV 25, 1985
AT		2.5%‡	N89074 001	NOV 26, 1985

OINTMENT; TOPICAL

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

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

SUSPENSION; OTIC

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

SUSPENSION/DROPS; OPHTHALMIC

	CORTISPORIN			
AT	BURROUGHS WELLCOME	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N50169 001	
	NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE			
AT	PHARMAFAIR	1%:EQ 3.5MG BASE/ML; 10,000 UNITS/ML‡	N62623 001	SEP 24, 1985

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

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

HYDROCORTISONE BUTYRATE (PAGE 3-116)

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

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

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

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

HYDROFLUMETHIAZIDE; RESERPINE (PAGE 3-117)

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

HYDROXYZINE HYDROCHLORIDE (PAGE 3-118)

INJECTABLE; INJECTION
HYDROXYZINE
AP ELKINS-SINN/AHROBINS 50MG/ML N85551 002
HYDROXYZINE HCL
/AP/ /ELKINS-SINN/AHROBINS/ 50MG/ML/ /N85551 002/
AP PHARMAFAIR 25MG/ML‡ N88862 001 FEB 14, 1986
AP 25MG/ML‡ N89106 001 FEB 14, 1986
AP 50MG/ML‡ N88881 001 FEB 14, 1986
AP 50MG/ML‡ N89107 001 FEB 14, 1986

HYDROXYZINE HYDROCHLORIDE (PAGE 3-118)

TABLET; ORAL
HYDROXYZINE HCL
AB AMIDE PHARMACEUTICAL 10MG‡ N89071 001 JUL 22, 1986
AB 25MG‡ N89072 001 JUL 22, 1986
AB 50MG‡ N89073 001 JUL 22, 1986
AB COLMED LABORATORIES 10MG‡ N89121 001 MAR 20, 1986
AB 25MG‡ N89122 001 MAR 20, 1986
AB 50MG‡ N89123 001 MAR 20, 1986
AB MUTUAL PHARM 10MG‡ N89381 001 MAY 19, 1986
AB 25MG‡ N89382 001 MAY 19, 1986
AB 50MG‡ N89383 001 MAY 19, 1986
AB QUANTUM PHARMICS 10MG‡ N88540 001 OCT 22, 1985
AB 25MG‡ N88551 001 OCT 22, 1985
AB 50MG‡ N88529 001 OCT 22, 1985
AB SIDMAK LABORATORIES 10MG‡ N88617 001 JAN 10, 1986
AB 25MG‡ N88618 001 JAN 10, 1986
AB 50MG‡ N88619 001 JAN 10, 1986

HYDROXYZINE PAMOATE (PAGE 3-120)

CAPSULE; ORAL
HYDROXYZINE PAMOATE
AB PAR PHARMACEUTICAL EQ 25MG HCL‡ N89145 001 MAR 17, 1986
AB EQ 50MG HCL‡ N89146 001 MAR 17, 1986

IBUPROFEN (PAGE 3-120)

TABLET; ORAL
IBUPROFEN

AB	BOOTS PHARMACEUTICAL	400MG	N71264 001	JUL 25, 1986
AB	CHELSEA LABORATORIES	400MG	N70038 001	SEP 06, 1985
AB		600MG	N70041 001	SEP 06, 1985
AB	CORD LABORATORIES	300MG	N70734 001	JUN 12, 1986
AB		400MG	N70735 001	JUN 12, 1986
AB		600MG	N70736 001	JUN 12, 1986
AB	DANBURY PHARMACAL	400MG	N70436 001	AUG 21, 1985
AB		600MG	N70437 001	AUG 21, 1985
>ADD> AB	INTERPHARM	400MG	N71334 001	NOV 25, 1986
>ADD>				
>ADD> AB		600MG	N71335 001	NOV 25, 1986
>ADD>				
AB	LEDERLE LABS/AM CYAN	400MG	N70629 001	SEP 19, 1986
AB		600MG	N70630 001	SEP 19, 1986
AB	MCNEIL CONSUMER PROD	400MG	N70081 001	JUN 16, 1986
AB		600MG	N70476 001	JUN 16, 1986
AB	MUTUAL PHARM	300MG	N71230 001	OCT 22, 1986
AB		400MG	N71231 001	OCT 22, 1986
AB		600MG	N71232 001	OCT 22, 1986
AB	MYLAN PHARMS	400MG	N70045 001	SEP 24, 1985
AB		600MG	N70057 001	SEP 24, 1985
AB	OHM LABORATORIES	400MG	N70818 001	DEC 26, 1985
AB	/$/PAR PHARMACEUTICAL	300MG	N70328 001	AUG 06, 1985
AB		400MG	N70329 001	AUG 06, 1985
AB		600MG	N70330 001	AUG 06, 1985
AB		800MG	N70986 001	JUL 25, 1986
AB	PRIVATE FORMULATIONS	300MG	N71266 001	OCT 15, 1986

IBUPROFEN (PAGE 3-120)

TABLET; ORAL
IBUPROFEN

AB		400MG	N71267 001	OCT 15, 1986
AB		600MG	N71268 001	OCT 15, 1986
AB	PUREPAC/KALIPHARMA	300MG	N71123 001	SEP 19, 1986
AB		400MG	N71124 001	SEP 19, 1986
AB		600MG	N71125 001	SEP 19, 1986
AB	SUPERPHARM	400MG	N70708 001	APR 25, 1986
AB		600MG	N70709 001	APR 25, 1986

IBUPROHM

AB	OHM LABORATORIES	400MG	N70469 001	AUG 29, 1985

IFEN

AB	LUCHEM PHARMS	400MG	N71145 001	SEP 23, 1986
AB		600MG	N71146 001	SEP 23, 1986

MOTRIN

>DLT> AB	/$/UPJOHN	300MG	N17463 003	
AB		800MG	N17463 005	MAY 22, 1985

RUFEN

AB	BOOT PHARMACEUTICAL	800MG	N70745 001	JUL 23, 1986

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 (PAGE 3-122)

CAPSULE; ORAL
INDOMETHACIN

AB	BARR LABORATORIES	25MG	N70067 001	OCT 03, 1986
AB		50MG	N70068 001	OCT 03, 1986
AB	BOLAR PHARMACEUTICAL	25MG	N70784 001	AUG 20, 1986
AB		50MG	N70785 001	AUG 20, 1986
AB	DURAMED PHARMS	25MG	N70326 001	OCT 18, 1985
AB		50MG	N70327 001	OCT 18, 1985
AB	MYLAN PHARMS	50MG	N70624 001	SEP 04, 1985
AB	PAR PHARMACEUTICAL	50MG	N70651 001	MAR 05, 1986
AB	PIONEER PHARMS	25MG	N70813 001	AUG 11, 1986
AB		50MG	N70592 001	AUG 11, 1986
AB	SUPERPHARM	25MG	N70487 001	OCT 10, 1986
AB		50MG	N70488 001	OCT 10, 1986
AB	WATSON LABORATORIES	25MG	N70529 001	OCT 18, 1985
AB		50MG	N70530 001	OCT 18, 1985
AB	ZENITH LABORATORIES	25MG	N70719 001	FEB 12, 1986
AB		50MG	N70756 001	FEB 12, 1986

SUSPENSION; ORAL
INDOCIN

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

IOHEXOL (PAGE 3-123)

INJECTABLE; INJECTION
OMNIPAQUE 180

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

OMNIPAQUE 240

	WINTHROP-BREON/STERL	51.8%	N18956 002	DEC 26, 1985

OMNIPAQUE 300

	WINTHROP-BREON/STERL	64.7%	N18956 003	DEC 26, 1985

OMNIPAQUE 350

	WINTHROP-BREON/STERL	75.5%	N18956 004	DEC 26, 1985

IOPAMIDOL (PAGE 3-123)

INJECTABLE; INJECTION
ISOVUE-300

	ER SQUIBB AND SONS	61%	N18735 002	DEC 31, 1985

ISOVUE-370

	ER SQUIBB AND SONS	76%	N18735 003	DEC 31, 1985

ISOVUE-M 200

	ER SQUIBB AND SONS	41%	N18735 001	DEC 31, 1985

ISOVUE-M 300

	ER SQUIBB AND SONS	61%	N18735 004	DEC 31, 1985

ISOETHARINE HYDROCHLORIDE (PAGE 3-124)

SOLUTION; INHALATION
ISOETHARINE HCL S/F

AN	DEY LABORATORIES	1%	N89252 001	SEP 15, 1986

ISONIAZID (PAGE 3-125)

SYRUP; ORAL
LANIAZID

AA	LANNETT	50MG/5ML	N89243 001	FEB 03, 1986

ISOSORBIDE DINITRATE (PAGE 3-126)

TABLET; ORAL
ISOSORBIDE DINITRATE

	BARR LABORATORIES	5MG	N86166 001	SEP 19, 1986
		10MG	N86169 001	SEP 19, 1986
		20MG	N86167 001	SEP 19, 1986
		30MG	N87564 001	SEP 18, 1986

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE

	BARR LABORATORIES	2.5MG	N84204 001	SEP 18, 1986
		5MG	N86168 001	SEP 18, 1986
		10MG	N87545 001	SEP 18, 1986

KANAMYCIN SULFATE (PAGE 3-126)

INJECTABLE; INJECTION
KANAMYCIN SULFATE

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

KETOCONAZOLE (PAGE 3-127)

CREAM; TOPICAL
NIZORAL

	JANSSEN PHARMA	2%*	N19084 001	DEC 31, 1985

> ADD > SUSPENSION; ORAL
> ADD > NIZORAL

> ADD >	JANSSEN PHARM	100MG/5ML*	N70767 001	NOV 07, 1986

KETOPROFEN (PAGE 3-127)

CAPSULE; ORAL
ORUDIS

	NYETH LABS/AMHO	50MG*	N18754 002	JAN 09, 1986
		75MG*	N18754 003	JAN 09, 1986

LABETALOL HYDROCHLORIDE (PAGE 3-127)

INJECTABLE; INJECTION
NORMODYNE

AP	SCHERING	5MG/ML	N18686 001	AUG 01, 1984

TRANDATE

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

LACTULOSE (PAGE 3-127)

SYRUP; ORAL
LACTULOSE

AA	ROXANE LABORATORIES	10GM/15ML	N17906 001	

LEUCOVORIN CALCIUM (PAGE 3-127)

TABLET; ORAL
LEUCOVORIN CALCIUM

BX	LEDERLE LABS/AM CYAN	EQ 5MG BASE*	N18459 001	JAN 30, 1986

WELLCOVORIN

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

LEVOBUNOLOL HYDROCHLORIDE (PAGE 3-128)

SOLUTION/DROPS; OPHTHALMIC
BETAGAN

	ALLERGAN PHARMS	0.5%*	N19219 002	DEC 19, 1985

LITHIUM CITRATE (PAGE 3-132)

SYRUP; ORAL
LITHIUM CITRATE

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

LORAZEPAM (PAGE 3-132)

TABLET; ORAL
ATIVAN

AB	NYETH LABS/AMHO	0.5MG	N17794 001	
AB		1MG	N17794 002	
AB		2MG	N17794 003	

LORAZEPAM (PAGE 3-132)

TABLET; ORAL
LORAZEPAM

AB	AM THERAPEUTIC	0.5MG*	N70727 001	MAR 07, 1986
AB		1MG*	N70728 001	MAR 07, 1986
AB		2MG*	N70729 001	MAR 07, 1986

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	DANBURY PHARMACAL	0.5MG*	N71117 001	JUL 24, 1986
AB		1MG*	N71118 001	JUL 24, 1986
AB		2MG*	N71110 001	JUL 24, 1986
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

MAGNESIUM SULFATE (PAGE 3-134)

INJECTABLE; INJECTION
MAGNESIUM SULFATE

	LYPHOMED	500MG/ML*	N19316 001 SEP 08, 1986

MANGANESE CHLORIDE (PAGE 3-134)

INJECTABLE; INJECTION
MANGANESE CHLORIDE IN PLASTIC CONTAINER

	ABBOTT LABORATORIES	EQ 0.1MG MANGANESE/ML*	N18962 001 JUN 26, 1986

MANNITOL (PAGE 3-134)

SOLUTION; IRRIGATION
RESECTISOL

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

RESECTISOL IN PLASTIC CONTAINER

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

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

TABLET; ORAL
MECLIZINE HCL

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

MECLOFENAMATE SODIUM (PAGE 3-136)

CAPSULE; ORAL
MECLOFENAMATE SODIUM

> ADD > AB	ROLAR PHARMACEUTICAL	EQ 50MG BASE*	N70400 001	NOV 25, 1986
> ADD > AB		EQ 100MG BASE*	N70401 001	NOV 25, 1986
AB	MYLAN PHARMS	EQ 50MG BASE*	N71080 001	SEP 03, 1986
AB		EQ 100MG BASE*	N71081 001	SEP 03, 1986

MECLOMEN

AB	PARKE-DAVIS/W-L	EQ 50MG BASE	N18006 001
AB		EQ 100MG BASE	N18006 002

MEDROXYPROGESTERONE ACETATE (PAGE 3-136)

TABLET; ORAL
PROVERA

	UPJOHN	5MG	N11839 003

MENOTROPINS (PAGE 1-137)

INJECTABLE; INJECTION

PERGONAL

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

METAPROTERENOL SULFATE (PAGE 3-140)

SOLUTION; INHALATION

ALUPENT

BOEHRINGER INGELHEIM	0.4%		N18761 002
			OCT 10, 1986

METHACHOLINE CHLORIDE (PAGE 3-140)

POWDER FOR RECONSTITUTION; INHALATION

PROVOCHOLINE

HOFFMANN-LA ROCHE	100MG/VIAL		N19193 001
			OCT 31, 1986

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
>DLT >/AP/		/EQ 25MG BASE/ML/	/N89181 001/
>DLT >			/JAN 03, 1986/
>DLT >/AP/		/EQ 25MG BASE/ML/	/N89182 001/
>DLT >			/JAN 03, 1986/

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION

METHOTREXATE LPF

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

METHOTREXATE SODIUM

AP	BEN VENUE LABS	EQ 25MG BASE/ML	N89340 001
			SEP 16, 1986
AP		EQ 25MG BASE/ML	N89341 001
			SEP 16, 1986
AP		EQ 25MG BASE/ML	N89342 001
			SEP 16, 1986
AP		EQ 25MG BASE/ML	N89343 001
			SEP 16, 1986
AP	INTL PHARM PRODS	EQ 25MG BASE/ML	N88648 001
			MAY 09, 1986
AP	LYPHOMED	EQ 2.5MG BASE/ML	N89323 001
			JUN 13, 1986
AP		EQ 20MG BASE/VIAL	N88935 001
			OCT 11, 1985
AP		EQ 25MG BASE/ML	N89322 001
			JUN 13, 1986
AP		EQ 25MG BASE/ML	N89263 001
			JUN 13, 1986
AP		EQ 50MG BASE/VIAL	N88936 001
			OCT 11, 1985
AP		EQ 100MG BASE/VIAL	N88937 001
			OCT 11, 1985
AP	QUAD PHARMS	EQ 25MG BASE/ML	N89308 001
			JUL 10, 1986
AP		EQ 25MG BASE/ML	N89309 001
			JUL 10, 1986
AP		EQ 20MG BASE/VIAL	N89293 001
			JUL 10, 1986
AP		EQ 50MG BASE/VIAL	N89294 001
			JUL 10, 1986
AP		EQ 100MG BASE/VIAL	N89295 001
			JUL 10, 1986
AP		EQ 250MG BASE/VIAL	N89296 001
			JUL 10, 1986

METHOTREXATE

AP	LEDERLE LABS/AM CYAN	EQ 2.5MG BASE/ML	N11719 004

MEXATE

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

METHOXSALEN (PAGE 3-143)

CAPSULE, LIQUID FILLED; ORAL

OXSORALEN-ULTRA

ELDER PHARMS	10MG		N19600 001
			OCT 30, 1986

METHYCLOTHIAZIDE (PAGE 3-143)

TABLET; ORAL
METHYCLOTHIAZIDE

AB	PAR PHARMACEUTICAL	2.5MG¤	N89135 001 FEB 12, 1986
AB		5MG¤	N89136 001 FEB 12, 1986

METHYLDOPA (PAGE 3-144)

TABLET; ORAL
METHYLDOPA

AB	BARR LABORATORIES	125MG¤	N70073 001 OCT 09, 1986
AB		250MG¤	N70060 001 OCT 09, 1986
AB		500MG¤	N70074 001 OCT 09, 1986
AB	BOLAR PHARMACEUTICAL	125MG¤	N70245 001 FEB 25, 1986
AB		250MG¤	N70246 001 FEB 25, 1986
AB		500MG¤	N70247 001 FEB 25, 1986
AB	DANBURY PHARMACAL	250MG¤	N70703 001 JUN 06, 1986
AB		500MG¤	N70625 001 JUN 06, 1986
AB	LEDERLE LABS/AM CYAN	125MG¤	N70070 003 OCT 15, 1985
AB		250MG¤	N70084 001 OCT 15, 1985
AB		500MG¤	N70085 001 OCT 15, 1985
AB	PARKE-DAVIS/W-L	125MG¤	N70331 001 APR 15, 1986
AB		250MG¤	N70332 001 APR 15, 1986
AB		500MG¤	N70333 001 APR 15, 1986
AB	PUREPAC/KALIPHARMA	125MG¤	N70749 001 FEB 07, 1986
AB		250MG¤	N70750 001 FEB 07, 1986
AB		500MG¤	N70452 001 FEB 07, 1986
AB	ROXANE LABORATORIES	125MG¤	N70192 001 APR 25, 1986
AB		250MG¤	N70193 001 APR 25, 1986
AB		500MG¤	N70194 001 APR 25, 1986

METHYLDOPA (PAGE 3-144)

TABLET; ORAL
METHYLDOPA

AB	ZENITH LABORATORIES	250MG¤	N70098 001 FEB 20, 1986
AB		500MG¤	N70343 001 FEB 20, 1986

METHYLDOPATE HYDROCHLORIDE (PAGE 3-144)

INJECTABLE; INJECTION
ALDOMET

AP	MS&D/MERCK	50MG/ML	N13401 001

METHYLDOPATE HCL

AP	ELKINS-SINN/AHROBINS	50MG/ML¤	N70291 001 JUL 01, 1986
AP	LYPHOMED	50MG/ML¤	N70652 001 JUN 03, 1986
AP	QUAD PHARM	50MG/ML¤	N71024 001 SEP 18, 1986

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-145)

INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE

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

METOCLOPRAMIDE HCL

AP	LYPHOMED	EQ 10MG BASE/2ML¤	N70203 001 JAN 24, 1986
AP	QUAD PHARMS	EQ 10MG BASE/2ML¤	N70671 001 MAY 27, 1986

REGLAN

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

TABLET; ORAL

CLOPRA-"YELLOW"

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

MAXOLON

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

METOCLOPRAMIDE HCL

AB	CHELSEA LABORATORIES	EQ 10MG BASE¤	N70453 001 JUN 06, 1986
AB	DANBURY PHARMACAL	EQ 10MG BASE¤	N70511 001 JAN 22, 1986
AB	HALSEY DRUG	EQ 10MG BASE¤	N70906 001 OCT 28, 1986
AB	INTERPHARM	EQ 10MG BASE¤	N71213 001 SEP 24, 1986
AB	PAR PHARMACEUTICAL	EQ 10MG BASE¤	N70342 001 MAR 25, 1986
AB	PUREPAC/KALIPHARMA	EQ 10MG BASE¤	N70581 001 OCT 17, 1985

METRONIDAZOLE (PAGE 3-148)

INJECTABLE; INJECTION

METRONIDAZOLE

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

TABLET; ORAL

METRONIDAZOLE

AB	HALSEY DRUG	500MG¤	N70593 001 FEB 27, 1986
AB	MUTUAL PHARM	250MG¤	N70772 001 JUL 16, 1986
AB		500MG¤	N70773 001 JUL 16, 1986
AB	VITARINE	250MG	N18620 001 MAR 04, 1982
AB		500MG	N18620 002 JUN 02, 1983

METRONIDAZOLE (PAGE 3-148)

TABLET; ORAL

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/
	ETHITEK PHARMS	100%¤	N19368 001 OCT 29, 1985

MORPHINE SULFATE (PAGE 3-150)

INJECTABLE; INJECTION

ASTRAMORPH PF

AP	ASTRA PHARM PRODS	0.5MG/ML¤		N71050 001
				OCT 07, 1986
AP		0.5MG/ML¤		N71051 001
				OCT 07, 1986
AP		1MG/ML¤		N71052 001
				OCT 07, 1986
AP		1MG/ML¤		N71053 001
				OCT 07, 1986

DURAMORPH PF

AP	ELKINS-SINN/AHROBINS	0.5MG/ML		N18565 001
				SEP 18, 1984
AP		1MG/ML		N18565 002
				SEP 18, 1984

NABILONE (PAGE 3-150)

CAPSULE; ORAL

CESAMET

	ELI LILLY	1MG¤		N18677 001
				DEC 26, 1985

NADOLOL (PAGE 3-150)

TABLET; ORAL

CORGARD

	ER SQUIBB AND SONS	20MG¤		N18063 005
				OCT 28, 1986

NALBUPHINE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

NALBUPHINE

AP	LYPHOMED	10MG/ML¤		N70751 001	> ADD >
				JUL 02, 1986	> ADD >
AP		20MG/ML¤		N70752 001	> ADD >
			SEP 24, 1986 :	JUL 02, 1986	> ADD >
AP	QUAD PHARMS	10MG/ML¤		N70692 001	> ADD >
				MAR 25, 1986	> ADD >
AP		20MG/ML¤		N70693 001	
			SEP 24, 1986 :	MAR 25, 1986	

NUBAIN

AP	DUPONT PHARMS/DUPONT	10MG/ML		N18024 001
AP		20MG/ML		N18024 002
				MAY 27, 1982

NALIDIXIC ACID (PAGE 3-151)

TABLET; ORAL

NALIDIXIC ACID

AB	BARR LABORATORIES	250MG¤		N70270 001
			JUN 29, 1988 :	MAR 28, 1986
AB		500MG¤		N70271 001
			JUN 29, 1988 :	MAR 28, 1986
AB		1GM¤		N70272 001
			JUN 29, 1988 :	MAR 28, 1986

NEGGRAM

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

NALOXONE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

NALOXONE

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

NALOXONE HCL

AP	LYPHOMED	0.02MG/ML¤		N70648 001
				NOV 17, 1986
AP		0.02MG/ML¤		N70661 001
				NOV 17, 1986
AP		0.4MG/ML¤		N70649 001
				NOV 17, 1986
AP	WINTHROP-BREON/STERL	0.02MG/ML¤		N70171 001
			SEP 24, 1986 :	APR 18, 1986
AP		0.4MG/ML¤		N70172 001
			SEP 24, 1986 :	APR 18, 1986

NARCAN

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

/3/

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE (PAGE 3-151)

TABLET; ORAL
TALWIN NX
~~/WINTHROP-BREON/STERL/0.5 MG;EQ 50MG BASE/ /N18733 001/ /DEC 16, 1982/~~

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

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION
DECA-DURABOLIN

AO	ORGANON/AKZONA	50MG/ML¤	N13132 001 JUN 12, 1986
AO		100MG/ML¤	N13132 002 JUN 12, 1986
AO		200MG/ML¤	N13132 003 JUN 12, 1986

NANDROLONE DECANOATE

AO	CARTER-GLOGAU LABS	50M/ML	N86385 001 JAN 13, 1984
AO		100MG/ML	N86598 001 JAN 13, 1984
AO	LEMMON	50MG/ML¤	N88554 001 FEB 10, 1986
AO		50MG/ML	N87598 001 OCT 06, 1983
AO	QUAD PHARMS	50MG/ML¤	N89248 001 JUN 25, 1986
AO		100MG/ML¤	N89249 001 JUN 25, 1986
AO		200MG/ML¤	N89250 001 JUN 25, 1986

NANDROLONE PHENPROPIONATE (PAGE 3-151)

INJECTABLE; INJECTION
NANDROLONE PHENPROPIONATE

AO	QUAD PHARMS	25MG/ML¤	N89297 001 OCT 01, 1986
AO		50MG/ML¤	N89298 001 OCT 01, 1986

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

SOLUTION; IRRIGATION
NEOMYCIN AND POLYMYXIN B SULFATES

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

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

SOLUTION; IRRIGATION
NEOSPORIN G.U. IRRIGANT

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

NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE (3-153)

CREAM; TOPICAL
MYTREX A

AT	SAVAGE LABS/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62598 001 JUL 21, 1986

NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE

AT	E FOUGERA/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62600 001 JUL 21, 1986
AT	PHARMADERM/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62595 001 JUL 21, 1986

OINTMENT; TOPICAL
MYTREX A

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

NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE

AT	E FOUGERA/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62608 001 MAY 23, 1986
AT	PHARMADERM/ALTANA	EQ 3.5MG BASE/GM;0.1%¤	N62607 001 MAY 23, 1986

NIFEDIPINE (PAGE 3-154)

CAPSULE; ORAL
ADALAT

AB	MILES PHARM/MILES	10MG¤	N19478 001 NOV 27, 1985
AB		20MG¤	N19478 002 SEP 17, 1986

PROCARDIA

AB	PFIZER LABS/PFIZER	10MG	N18482 001
AB		20MG¤	N18482 002 JUL 24, 1986

NITROGLYCERIN (PAGE 3-154)

AEROSOL; ORAL
NITROLINGUAL

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

NITROGLYCERIN (PAGE 3-154)

INJECTABLE; INJECTION
NITROGLYCERIN

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

/NOMIFENSINE MALEATE/ (PAGE 3-155)

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

NORFLOXACIN (PAGE 3-155)

TABLET; ORAL
NOROXIN

	MS&D RES LABS/MERCK	200MG¤	N19384 001 OCT 31, 1986
		400MG¤	N19384 002 OCT 31, 1986

NYSTATIN (PAGE 3-156)

OINTMENT; TOPICAL
MYKINAC

AT	NMC LABORATORIES	100,000 UNITS/GM¤	N62731 001 SEP 22, 1986

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

NYSTATIN (PAGE 3-156)

TABLET; ORAL
NYSTATIN

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

TABLET; VAGINAL
NYSTATIN

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

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

CREAM; TOPICAL
MYCO-TRIACET II

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

MYTREX F

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

NYSTATIN-TRIAMCINOLONE ACETONIDE

AT	E FOUGERA/ALTANA	100,000 UNITS/GM;0.1%¤	N62599 001 OCT 08, 1985
AT	PHARMADERM/ALTANA	100,000 UNITS/GM;0.1%¤	N62596 001 OCT 08, 1985

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT	PHARMAFAIR	100,000 UNITS/GM;0.1%¤	N62657 001 JUL 30, 1986

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

AT	E FOUGERA/ALTANA	100,000 UNITS/GM;0.1%¤	N62602 001 OCT 09, 1985
AT	PHARMADERM/ALTANA	100,000 UNITS/GM;0.1%¤	N62603 001 OCT 09, 1985

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT	CLAY-PARK LABS	100,000 UNITS/GM;0.1%¤	N62280 002 OCT 10, 1985
AT	PHARMAFAIR	100,000 UNITS/GM;0.1%¤	N62656 002 JUL 30, 1986

OXYPHENBUTAZONE (PAGE 3-159)

TABLET; ORAL
OXYPHENBUTAZONE
AB ∂ BOLAR PHARMACEUTICAL 100MG N88399 001 SEP 17, 1984

PARGYLINE HYDROCHLORIDE (PAGE 3-160)

TABLET; ORAL
EUTONYL
∂ ABBOTT LABORATORIES 50MG N13448 004

PENICILLIN G POTASSIUM (PAGE 3-161)

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN G POTASSIUM
AA ∂ MYLAN PHARMS 200,000 UNITS/5ML N60752 003
AA ∂ 250,000 UNITS/5ML N60752 002
AA ∂ 400,000 UNITS/5ML N60752 001

PERMETHRIN (PAGE 3-164)

LOTION; TOPICAL
NIX
BURROUGHS WELLCOME 1%‡ N19435 001 MAR 31, 1986

PHENTERMINE HYDROCHLORIDE (PAGE 3-167)

CAPSULE; ORAL
ADIPEX
/AA/ /LEMMON/ /30MG/ N87126 001
PHENTERMINE HCL
AA DURAMED PHARMS 30MG‡ N88948 001 APR 25, 1986
AA LEMMON 30MG‡ N87777 001 NOV 01, 1985
AA 30MG N87126 001

PHENYLBUTAZONE (PAGE 3-168)

CAPSULE; ORAL
PHENYLBUTAZONE
AB BARR LABORATORIES 100MG‡ N88994 001 DEC 04, 1985

PHENYLBUTAZONE (PAGE 3-168)

TABLET; ORAL
PHENYLBUTAZONE
AB BARR LABORATORIES 100MG‡ N88863 001 DEC 04, 1985

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-168)

SYRUP; ORAL
PROMETHAZINE VC PLAIN
AA HR CENCI LABS 5MG/5ML;6.25MG/5ML‡ N88815 001 NOV 22, 1985

PHENYTOIN SODIUM, EXTENDED (PAGE 3-169)

CAPSULE; ORAL
/EXTENDED PHENYTOIN SODIUM/
/AA/ /BOLAR PHARMACEUTICAL/100MG/ /N88711 001/ /DEC 21, 1984/
/SETROL/
PHENYTEX
AB BOLAR PHARMACEUTICAL 100MG N88711 001 DEC 21, 1984

PHENYTOIN SODIUM, PROMPT (PAGE 3-169)

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

PIPERAZINE CITRATE (PAGE 3-170)

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

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

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

POTASSIUM CHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

AP	MAURRY BIOLOGICAL	2MEQ/ML	N88286 001 SEP 05, 1985

TABLET, CONTROLLED RELEASE; ORAL
K-DUR 10

BC	KEY PHARMACEUTICALS	10MEQ	N19439 002 JUN 13, 1986

K-DUR 20

	KEY PHARMACEUTICALS	20MEQ	N19439 001 JUN 13, 1986

KALINORM

/BC/	/A/S BENZON/	/10MEQ/	/N19381 001 APR 16, 1986/
BC	CIBA/CIBA-GEIGY	10MEQ	N19381 001 APR 16, 1986

KLOR-CON

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

SLON-K

BC	CIBA-GEIGY	8MEQ	N17476 002

POTASSIUM CITRATE (PAGE 3-173)

/TABLET; ORAL/
TABLET, CONTROLLED RELEASE; ORAL
/POTASSIUM CITRATE/
UROCIT-K

	UNIV TX HLTH SCI CTR	5MEQ	N19071 001 AUG 30, 1985

PRALIDOXIME CHLORIDE (PAGE 3-174)

INJECTABLE; INJECTION
PRALIDOXIME CHLORIDE

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

/PROTOPAM/

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

PREDNISOLONE (PAGE 3-174)

SYRUP; ORAL
PRELONE

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

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-175)

SUSPENSION/DROPS; OPHTHALMIC
BLEPHAMIDE

AT	ALLERGAN PHARMS	0.2%;10%	N12813 002

PREDSULFAIR II

AT	PHARMAFAIR	0.2%;10%	N88837 001 DEC 24, 1985

PREDNISOLONE SODIUM PHOSPHATE (PAGE 3-176)

SOLUTION; ORAL
PEDIAPRED

	FISONS	EQ 5MG BASE/5ML	N19157 001 MAY 28, 1986

PREDNISONE (PAGE 3-176)

TABLET; ORAL
DELTASONE

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

ORASONE

/BX/	/REID-ROWELL LABS/	/1MG/	/N83009 001/
/BX/		/5MG/	/N83009 002/
/BX/		/10MG/	/N83009 003/
/BX/		/20MG/	/N83009 004/
/BX/		/50MG/	/N85999 001/
AB	REID-ROWELL LABS	1MG	N83009 001
AB		5MG	N83009 002
AB		10MG	N83009 003
AB		20MG	N83009 004
AB		50MG	N85999 001

PREDNISONE

>ADD>	AB	AM THERAPEUTICS	5MG	N89387 001 NOV 06, 1986
>ADD>	AB		10MG	N89388 001 NOV 06, 1986
>ADD>	AB		20MG	N89389 001 NOV 06, 1986
>ADD>				
/BX/		/BARR LABORATORIES/	/5MG/	/N80701 001/
/BX/			/10MG/	/N86595 001/
/BX/			/20MG/	/N84634 001/
AB		BARR LABORATORIES	5MG	N80701 001
AB			10MG	N86595 001
AB			20MG	N84634 001
/BX/		/DANBURY PHARMACAL/	/5MG/	/N80356 001/
/BX/			/10MG/	/N85162 001/
/BX/			/20MG/	/N85161 001/

PREDNISONE (PAGE 3-176)

TABLET; ORAL
PREDNISONE

	AB	DANBURY PHARMACAL	5MG	N80356 001	
	AB		10MG	N85162 001	
	AB		20MG	N85161 001	
	/BX/	/DURAMED PHARMS/	/5MG/	/N88394 001/	
	/BX/		/10MG/	/N88395 001/	
	/BX/		/20MG/	/N88396 001/	
	AB	DURAMED PHARMS	5MG	N88394 001	
				OCT 04, 1983	
	AB		10MG	N88395 001	
				OCT 04, 1983	
	AB		20MG	N88396 001	
				OCT 04, 1983	
	AB	MUTUAL PHARM	5MG¤	N89245 001	
				DEC 04, 1985	
	AB		10MG¤	N89246 001	
				DEC 04, 1985	
	AB		20MG¤	N89247 001	
				DEC 04, 1985	
	/BX/	/PRIVATE FORMULATIONS/	/5MG/	/N88269 001/	
	/BX/		/20MG/	/N85151 001/	
	AB	PRIVATE FORMULATIONS	5MG	N80209 001	
	AB		20MG	N85151 001	
	/BX/	/ROXANE LABORATORIES/	/1MG/	/N87800 001/	
				/APR 22, 1982/	
	/BX/		/2.5MG/	/N87801 001/	
				/APR 22, 1982/	
	/BX/		/5MG/	/N80352 001/	
	/BX/		/10MG/	/N84122 001/	
	/BX/		/25MG/	/N87833 001/	
				/MAY 04, 1982/	
	/BX/		/50MG/	/N84283 001/	
	AB	ROXANE LABORATORIES	1MG	N87800 001	
				APR 22, 1982	
	AB		2.5MG	N87801 001	
				APR 22, 1982	
	AB		5MG	N80352 001	
	AB		10MG	N84122 001	
> ADD >	AB		20MG	N87342 001	
	AB		25MG	N87833 001	
				MAY 04, 1982	
	AB		50MG	N84283 001	
	AB	TOWNE PAULSEN	10MG¤	N89028 001	
				JUL 24, 1986	
	/BX/	/WEST-WARD/	/5MG/	/N80292 001/	
	/BX/		/50MG/	/N88465 001/	
	AB	WEST-WARD	5MG	N80292 001	
	AB		10MG¤	N88832 001	
				DEC 04, 1985	
> ADD >	AB		20MG	N83677 001	
> DLT >	/BX/		/20MG/	/N83677 001/	
	AB		50MG	N88465 001	
				JUN 01, 1984	

PREDNISONE (PAGE 3-176)

TABLET; ORAL

> DLT >		/ROXANE LABORATORIES/	/20MG/		/N87342 001/
	/BX/	/ROXANE LABORATORIES/	/20MG/		/N87342 001/
> DLT >	AB/	/ROXANE LABORATORIES/	/20MG/		/N87342 001/

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

CAPSULE; ORAL
PROCAINAMIDE HCL

	AB	CORD LABORATORIES	250MG¤	N89219 001
				JUL 01, 1986
	AB		375MG¤	N89220 001
				JUL 01, 1986
	AB		500MG¤	N89221 001
				JUL 01, 1986

INJECTABLE; INJECTION
PROCAINAMIDE HCL

	AP	ABBOTT LABORATORIES	100MG/ML¤	N89069 001
				FEB 12, 1986
	AP		500MG/ML¤	N89070 001
				FEB 12, 1986
	AP	ELKINS-SINN/AHROBINS	100MG/ML¤	N89029 001
				APR 17, 1986
	AP		500MG/ML¤	N89030 001
				APR 17, 1986
> ADD >	AP	LYPHOMED	100MG/ML¤	N89415 001
> ADD >				NOV 17, 1986
> ADD >	AP		500MG/ML¤	N89416 001
> ADD >				NOV 17, 1986
	AP	PHARMAFAIR	100MG/ML¤	N88824 001
				NOV 20, 1985
	AP		500MG/ML¤	N88830 001
				NOV 20, 1985
	AP	QUAD PHARMS	100MG/ML¤	N89256 001
				MAY 30, 1986
	AP		500MG/ML¤	N89257 001
				MAY 30, 1986

TABLET, CONTROLLED RELEASE; ORAL
PROCAINAMIDE HCL

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

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

SYRUP; ORAL
PROMETHAZINE

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

TABLET; ORAL
PROMETHAZINE HCL

BP	LEMMON	25MG	N89109 001 SEP 10, 1985

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

INJECTABLE; INJECTION
INDERAL

AP	AYERST LABS/AMHO	1MG/ML	N16419 001

PROPRANOLOL HCL

AP	SOLOPAK LABORATORIES	1MG/ML	N70135 001 APR 15, 1986
AP		1MG/ML	N70136 001 APR 15, 1986
AP		1MG/ML	N70137 001 APR 15, 1986

TABLET; ORAL
INDERAL

AB	AYERST LABS/AMHO	60MG	N16418 009 OCT 18, 1982
AB		90MG	N16418 010 OCT 18, 1982

PROPRANOLOL

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

PROPRANOLOL HCL

AB	BARR LABORATORIES	10MG	N70319 001 OCT 22, 1985
AB		20MG	N70320 001 OCT 22, 1985
AB		40MG	N70103 001 OCT 22, 1985
AB		60MG	N70321 001 SEP 24, 1986 : SEP 15, 1986
AB		80MG	N70322 001 AUG 04, 1986

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL
PROPRANOLOL HCL

AB	CORD LABORATORIES	10MG	N70663 001 JUN 13, 1986
AB		20MG	N70664 001 JUN 13, 1986
AB		40MG	N70665 001 JUN 13, 1986
AB		60MG	N70666 001 OCT 10, 1986
AB		80MG	N70667 001 JUN 13, 1986
AB	DANBURY PHARMACAL	10MG	N70175 001 MAY 13, 1986
AB		20MG	N70176 001 MAY 13, 1986
AB		40MG	N70177 001 MAY 13, 1986
AB		60MG	N71098 001 OCT 06, 1986
AB		80MG	N70178 001 MAY 13, 1986
AB		90MG	N71183 001 OCT 06, 1986
AB	DUPAMED PHARMS	10MG	N70306 001 SEP 09, 1985
AB		20MG	N70307 001 SEP 09, 1985
AB		40MG	N70308 001 SEP 09, 1985
AB		60MG	N70309 001 OCT 01, 1986
AB		80MG	N70310 001 SEP 09, 1985
AB		90MG	N71327 001 OCT 01, 1986
AB	LEMMON	20MG	N70233 001 JUN 23, 1986
AB		40MG	N70234 001 JUN 23, 1986
AB	MARTEC PHARMS	10MG	N70120 001 AUG 06, 1985
AB		20MG	N70121 001 AUG 06, 1985
AB		40MG	N70122 001 AUG 06, 1985
AB		60MG	N70123 001 OCT 29, 1986
AB		80MG	N70124 001 AUG 06, 1985

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL
PROPRANOLOL HCL

AB	PAR PHARMACEUTICAL	10MG		N70217 001	AUG 01, 1986
AB		20MG		N70218 001	AUG 01, 1986
AB		40MG		N70219 001	AUG 01, 1986
AB		60MG		N70220 001	SEP 24, 1986 : JUN 05, 1986
AB		80MG		N70221 001	APR 14, 1986
AB		90MG		N71288 001	OCT 22, 1986
AB	PARKE-DAVIS/W-L	10MG		N70438 001	SEP 15, 1986
AB		20MG		N70439 001	SEP 15, 1986
AB		40MG		N70440 001	SEP 15, 1986
AB		60MG		N70441 001	SEP 24, 1986 : SEP 15, 1986
AB		80MG		N70442 001	SEP 15, 1986
> ADD > AB	PUREPAC/KALIPHARMA	10MG		N70814 001	NOV 03, 1986
> ADD > AB		20MG		N70815 001	NOV 03, 1986
> ADD > AB		40MG		N70816 001	NOV 03, 1986
> ADD > AB		60MG		N70817 001	NOV 03, 1986
> ADD > AB		80MG		N70757 001	NOV 03, 1986
AB	ROXANE LABORATORIES	10MG		N70516 001	JUL 07, 1986
AB		20MG		N70517 001	JUL 07, 1986
AB		40MG		N70518 001	JUL 07, 1986
AB		60MG		N70519 001	SEP 24, 1986 : SEP 11, 1986
AB		80MG		N70520 001	JUL 07, 1986
AB		90MG		N70521 001	SEP 24, 1986 : SEP 11, 1986
AB	WATSON LABS	10MG		N70548 001	JUL 10, 1986
AB		20MG		N70549 001	APR 11, 1986
AB		40MG		N70550 001	APR 11, 1986
AB		80MG		N70551 001	JUL 10, 1986

PROTAMINE SULFATE (PAGE 3-184)

INJECTABLE; INJECTION
PROTAMINE SULFATE

AP	ELI LILLY	10MG/ML		N06460 002
> ADD > AP	ELKINS-SINN/AHROBINS	10MG/ML		N89474 001 NOV 05, 1986
> ADD > AP		10MG/ML		N89475 001 NOV 05, 1986
AP	QUAD PHARMS	10MG/ML		N89306 001 MAY 30, 1986
AP		50MG/VIAL		N89307 001 MAY 30, 1986
AP	UPJOHN	50MG/VIAL		N07413 001

PROTEIN HYDROLYSATE (PAGE 3-184)

INJECTABLE; INJECTION
HYPROTIGEN 5%

KENDALL MCGAW LABS	5%		N06170 003 JAN 10, 1984

QUAZEPAM (PAGE 3-186)

TABLET; ORAL
DORMALIN

SCHERING	15MG		N18708 001 DEC 27, 1985

QUINIDINE GLUCONATE (PAGE 3-186)

TABLET, CONTROLLED RELEASE; ORAL
QUINALAN

BC LANNETT	324MG		N88081 001 FEB 10, 1986

QUINIDINE GLUCONATE

AB SUPERPHARM	324MG		N89164 001 NOV 21, 1985

RANITIDINE HYDROCHLORIDE (PAGE 3-187)

TABLET; ORAL
/ZANTAC/
/GLAXO/ /EQ 150MG BASE/ /N18703 001/ /JUN 09, 1983/

ZANTAC 150

GLAXO	EQ 150MG BASE		N18703 001 JUN 09, 1983

ZANTAC 300

GLAXO	EQ 300MG BASE		N18703 002 DEC 09, 1985

RIBAVIRIN (PAGE 3-189)

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

RITODRINE HYDROCHLORIDE (PAGE 3-189)

INJECTABLE; INJECTION
RITODRINE HCL
AP QUAD PHARMS 10MG/ML✠ N70700 001 OCT 06, 1986
AP 15MG/ML✠ N70701 001 OCT 06, 1986

YUTOPAR
AP ASTRA PHARM PRODS 10MG/ML N18580 001
AP 15MG/ML N18580 002

SECRETIN (PAGE 3-190)

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

SILVER SULFADIAZINE (PAGE 3-191)

CREAM; TOPICAL
SILVADENE
/AT/ /MARION LABORATORIES/ /1%/ /N17381 001/
AB MARION LABORATORIES 1% N17381 001
SSD
/AT/ /TRAVENOL LABS/ /1%/ /N18578 001/ /FEB 25, 1982/
AB TRAVENOL LABS 1% N18578 001 FEB 25, 1982 > ADD >
ULTRA DERM
AB CHESEBROUGH-PONDS 1%✠ N18810 001 DEC 23, 1985

SODIUM BICARBONATE (PAGE 3-191)

INJECTABLE; INJECTION
SODIUM BICARBONATE IN PLASTIC CONTAINER
ABBOTT LABORATORIES 0.9MEQ/ML✠ N19443 001 JUN 03, 1986
1MEQ/ML✠ N19443 002 JUN 03, 1986

SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-191)

GRANULE, EFFERVESCENT; ORAL
BAROS
MALLINCKRODT 460MG/GM;420MG/GM✠ N18509 001 AUG 07, 1985

SODIUM CHLORIDE (PAGE 3-191)

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

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

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

SODIUM NITROPRUSSIDE (PAGE 3-194)

INJECTABLE; INJECTION
NITROPRESS
AP ABBOTT LABORATORIES 50MG/VIAL✠ N70566 001 JUN 09, 1986

SODIUM POLYSTYRENE SULFONATE (PAGE 3-195)

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
AA ROXANE LABORATORIES 15GM/60ML✠ N89049 001 NOV 17, 1986 > ADD >

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

SPIRONOLACTONE (PAGE 3-196)

TABLET; ORAL

SPIRONOLACTONE

AB	MUTUAL PHARMACAL	25MG		N89424 001 JUL 23, 1986
> ADD > AB	SUPERPHARM	25MG		N89364 001 NOV 07, 1986
> ADD >				

STANOZOLOL (PAGE 3-196)

TABLET; ORAL

WINSTROL

	WINTHROP-BREON/STERL	2MG		N12885 001 MAY 14, 1984

SULCONAZOLE NITRATE (PAGE 3-197)

SOLUTION; TOPICAL

SULCOSYN

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

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

CREAM; VAGINAL

GYNE-SULF

AT	G AND W LABORATORIES	3.7%;2.86%;3.42%;0.64%		N88607 001 JUN 09, 1986

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

SUSPENSION; ORAL

SEPTRA GRAPE

AB	BURROUGHS WELLCOME	200MG/5ML;40MG/5ML		N17598 002 FEB 12, 1986

SULFAMETHOXAZOLE AND TRIMETHOPRIM

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

SUSPENSION; ORAL

SULMEPRIM

AB	MY-K LABS	200MG/5ML;40MG/5ML		N70063 001 AUG 01, 1986

SULMEPRIM PEDIATRIC

AB	MY-K LABS	200MG/5ML;40MG/5ML		N70064 001 AUG 01, 1986

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

> ADD > AB	CORD LABORATORIES	400MG;80MG		N70889 001 NOV 13, 1986
> ADD > AB		800MG;160MG		N70890 001 NOV 13, 1986
> ADD >				
AB	MUTUAL PHARM	400MG;80MG		N71016 001 AUG 25, 1986
AB		800MG;160MG		N71017 001 AUG 25, 1986
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

> DLT >	/AVC/			
> DLT >/AT/	/MERRELL DOW/DOW CHEM/15%/			/N065330 003/ /SEP 04, 1986/

VAGITROL

	LEMMON	15%		N88718 001 SEP 19, 1985

> DLT >	/SUPPOSITORY; VAGINAL/			
> DLT >	/AVC/			
> DLT >	/MERRELL DOW/DOW CHEM/1.65GM/			/N065331 004/ /SEP 04, 1986/
> DLT >				

SULFINPYRAZONE (PAGE 3-200)

CAPSULE; ORAL
SULFINPYRAZONE

AB	PAR PHARMACEUTICAL	200MG		N88934 001 SEP 06, 1985

TABLET; ORAL
SULFINPYRAZONE

AB	PAR PHARMACEUTICAL	100MG		N88933 001 SEP 06, 1985

SULFISOXAZOLE DIOLAMINE (PAGE 3-200)

SOLUTION/DROPS; OPHTHALMIC
SULFISOXAZOLE DIOLAMINE

AT	∂ BARNES-HIND PHARMS	EQ 4% BASE		N84148 001

GANTRISIN

AT	HOFFMAN-LAROCHE	EQ 4% BASE		N07757 002

SUPROFEN (PAGE 3-201)

CAPSULE; ORAL
SUPROL

	ORTHO PHARMACEUTICAL	200MG		N18217 001 DEC 24, 1985

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

INJECTABLE; INJECTION
/TECHNETIUM TC 99M SULFUR COLLOID/

	/GAMMA DIAG LABS/	/3MCI/ML/		/N17724 001/

SOLUTION; INJECTION, ORAL
TECHNETIUM TC 99M SULFUR COLLOID

	GAMMA DIAG LABS	3MCI/ML		N17724 001

TECHNETIUM, TC-99M, LIDOFENIN KIT (PAGE 3-202)

INJECTABLE; INJECTION
TECHNESCAN HIDA KIT

	MS&D RES LABS/MERCK	N/A		N18489 001 OCT 31, 1986

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

INJECTABLE; INJECTION
/SULFUR COLLOID KIT/

/AP/	/SYNCOR INTL/	/N/A/		/N17858 001/

AN-SULFUR COLLOID

AP	CIS-US	N/A		N17858 001

/TECHNECOLL/

/AP/	/MALLINCKRODT/	/N/A/		/N17059 001/

/TESULOID/

/AP/	/ER SQUIBB AND SONS/	/N/A/		/N16923 001/

SOLUTION; INJECTION, ORAL
TECHNECOLL

AP	MALLINCKRODT	N/A		N17059 001

TESULOID

AP	ER SQUIBB AND SONS	N/A		N16923 001

TEMAZEPAM (PAGE 3-203)

CAPSULE; ORAL
RESTORIL

AB	SANDOZ PHARMS/SANDOZ	15MG		N18163 001
AB		30MG		N18163 002

/SOMAZ/
TEMAZ

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

TEMAZEPAM

AB	BARR LABORATORIES	15MG		N71174 001 JUL 10, 1986
AB		30MG		N71175 001 JUL 10, 1986
AB	COLMED LABORATORIES	15MG		N70489 001 JUL 07, 1986
AB		30MG		N70490 001 JUL 07, 1986
AB	MYLAN PHARMS	15MG		N70919 001 JUL 07, 1986
AB		30MG		N70920 001 JUL 07, 1986

TESTOSTERONE ENANTHATE (PAGE 3-204)

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE

AO	QUAD PHARMS	100MG/ML		N89324 001 SEP 16, 1986
AO		200MG/ML		N89325 001 SEP 16, 1986

TESTOSTERONE PROPIONATE (PAGE 3-204)

INJECTABLE; INJECTION
TESTOSTERONE PROPIONATE

>ADD>	AO	QUAD PHARMS	100MG/ML	N89283 001	
>ADD>				NOV 03, 1986	

TETRACYCLINE HYDROCHLORIDE (PAGE 3-205)

CAPSULE; ORAL
TETRACYCLINE HCL

AB	PRIVATE FORMULATIONS	250MG	N62686 001	
			JUL 24, 1986	
AB		500MG	N62686 002	
			JUL 24, 1986	

THEOPHYLLINE (PAGE 3-206)

CAPSULE; ORAL
ELIXOPHYLLIN

/AA/	/BERLEX/SCHERING/	/100MG/	/N85545 001/	
			/JUL 31, 1984/	
/AA/		/200MG/	/N83921 001/	
			/JUL 31, 1984/	

SOMOPHYLLIN-T

/BP/	/FISONS/	/100MG/	/N87155 001/	
			/FEB 25, 1985/	
/BP/		/200MG/	/N87155 002/	
			/FEB 25, 1985/	
BX	BERLEX/SCHERING	100MG	N85545 001	
			JUL 31, 1984	
BX		200MG	N83921 001	
			JUL 31, 1984	

SOMOPHYLLIN-T

BX	FISONS	100MG	N87155 001	
			FEB 25, 1985	
BX		200MG	N87155 002	
			FEB 25, 1985	
>ADD> BX		250MG	N87155 003	
			FEB 25, 1985	

THEOPHYLLINE

>ADD> BX	RP SCHERER	100MG	N84731 002	
>ADD>			NOV 07, 1986	
>ADD> BX		200MG	N84731 001	
>ADD>			NOV 07, 1986	
>ADD> BX		250MG	N84731 003	
>ADD>			NOV 07, 1986	

CAPSULE, CONTROLLED RELEASE; ORAL
AEROLATE III

>ADD>	FLEMING	65MG	N85075 003	
>ADD>			NOV 24, 1986	

THEOPHYLLINE (PAGE 3-206)

CAPSULE, CONTROLLED RELEASE; ORAL
AEROLATE JR

>ADD> BC	FLEMING	130MG	N85075 002	
>ADD>			NOV 24, 1986	

AEROLATE SR

>ADD> BC	FLEMING	260MG	N85075 001	
>ADD>			NOV 24, 1986	

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	

THEOPHYLLINE-SR

BC	RP SCHERER	300MG	N88255 001	
			JUN 12, 1986	

ELIXIR; ORAL
THEOPHYL 225

	/KNOLL PHARMACEUTICAL/	112.5MG/15ML/	/N86485 001/	
	MCNEIL PHARM	112.5MG/15ML	N86485 001	

SYRUP; ORAL
ACCURDRON

AA	MERRELL DON/DOW CHEM	150MG/15ML	N88746 001	
			NOV 22, 1985	

THEOPHYLLINE

AA	NATL PHARM MFG/BARRE	150MG/15ML	N86545 001	

TABLET; ORAL
QUIBRON-T

	MEAD JOHNSON/B-M	300MG	N88656 001	
			AUG 22, 1985	

SLO-PHYLLIN

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

THEOPHYL-225

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

TABLET, CHEWABLE; ORAL
THEOPHYL

	MCNEIL PHARM	100MG	N86506 001	
			SEP 12, 1985	

TABLET, CONTROLLED RELEASE; ORAL
THEO-DUR

	KEY PHARMACEUTICALS	450MG	N89131 001	
			JUN 25, 1986	

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

TABLET; ORAL
THIORIDAZINE HCL

AB	CORD LABORATORIES	150MG*	N88136 001	SEP 17, 1986
AB		200MG*	N88137 001	SEP 17, 1986
AB	MUTUAL PHARM	10MG*	N89431 001	AUG 01, 1986
AB		25MG*	N89432 001	AUG 01, 1986
AB		50MG*	N89433 001	AUG 01, 1986

TIMOLOL MALEATE (PAGE 3-211)

SOLUTION/DROPS; OPHTHALMIC
TIMOPTIC IN OCUDOSE

>ADD>	MSD RES LABS	EQ 0.25% BASE*	N19463 001	NOV 05, 1986
>ADD>		EQ 0.5% BASE*	N19463 002	NOV 05, 1986

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	BOLAR PHARMACEUTICAL	100MG*	N70242 001	AUG 01, 1986
AB		250MG*	N70243 001	AUG 01, 1986
AB		500MG*	N70244 001	AUG 01, 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

AB	COLMED LABORATORIES	250MG*	N70168 001	APR 02, 1986
AB		500MG*	N70169 001	APR 02, 1986
AB	CORD LABORATORIES	250MG*	N70289 001	MAR 13, 1986
AB		500MG*	N70290 001	MAR 13, 1986
AB	DANBURY PHARMACAL	100MG*	N70513 001	JAN 09, 1986
AB		250MG*	N70514 001	JAN 09, 1986
AB		500MG*	N70515 001	JAN 09, 1986
AB	DURAMED PHARMS	100MG*	N70165 001	JAN 10, 1986
AB		250MG*	N70166 001	JAN 10, 1986
AB		500MG*	N70167 001	JAN 10, 1986
AB	INTERPHARM	250MG*	N71270 001	SEP 23, 1986
AB		500MG*	N71271 001	SEP 23, 1986
AB	MYLAN PHARMS	250MG*	N70259 001	JAN 02, 1986
AB		500MG*	N70913 001	MAR 17, 1986
AB	PAR PHARMACEUTICAL	100MG*	N70159 001	JAN 06, 1986
AB		250MG*	N70160 001	JAN 06, 1986
AB		500MG*	N70161 001	JAN 06, 1986
AB	SUPERPHARM	250MG*	N70763 001	JUN 16, 1986
AB		500MG*	N70764 001	JUN 16, 1986

TRAZODONE HYDROCHLORIDE (PAGE 3-212)

TABLET; ORAL
DESYREL

AB	MEAD JOHNSON/B-M	50MG	N18207 001	
AB		100MG	N18207 002	

TRAZODONE HYDROCHLORIDE (PAGE 3-212)

TABLET; ORAL
TRAZODONE HCL

AB	AM THERAPEUTICS	50MG		N71139 001 OCT 29, 1986
AB		100MG		N71140 001 OCT 29, 1986
> ADD > AB	BOLAR PHARMACEUTICAL	50MG		N71112 001 NOV 17, 1986
> ADD > AB		100MG		N71113 001 NOV 17, 1986
AB	CHELSEA LABORATORIES	50MG		N70568 001 OCT 10, 1986
AB		100MG		N70569 001 OCT 10, 1986
AB	DANBURY PHARMACAL	50MG		N70857 001 OCT 10, 1986
AB		100MG		N70858 001 OCT 10, 1986

TRIAMCINOLONE ACETONIDE (PAGE 3-213)

LOTION; TOPICAL
TRIAMCINOLONE ACETONIDE

AT	THAMES PHARMACAL	0.1%		N89129 001 AUG 14, 1986

PASTE; DENTAL
KENALOG IN ORABASE

AT	ER SQUIBB AND SONS	0.1%		N12097 001

ORACORT

AT	TARO PHARMS	0.1%		N70730 001 OCT 01, 1986

TRIENTINE HYDROCHLORIDE (PAGE 3-216)

CAPSULE; ORAL
CUPRID

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

TRIMETHOBENZAMIDE HYDROCHLORIDE (PAGE 3-217)

INJECTABLE; INJECTION
TRIMETHOBENZAMIDE HCL

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

TRIMETHOPRIM (PAGE 3-218)

TABLET; ORAL
TRIMETHOPRIM

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

TROPICAMIDE (PAGE 3-219)

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE

AT	MAURRY BIOLOGICAL	1%		N88447 001 AUG 28, 1985

UROFOLLITROPIN (PAGE 3-220)

INJECTABLE; INJECTION
METRODIN

	SERONO LABS	75IU/AMP		N19415 001 SEP 18, 1986

VALPROATE SODIUM (PAGE 3-220)

SYRUP; ORAL
DEPAKENE

AA	ABBOTT LABORATORIES	EQ 250MG BASE/5ML		N18082 001

MYPROIC ACID

AA	MY-K LABS	EQ 250MG BASE/5ML		N70868 001 JUL 01, 1986

VALPROIC ACID (PAGE 3-220)

CAPSULE; ORAL
DEPAKENE

AB	ABBOTT LABORATORIES	250MG		N18081 001

VALPROIC ACID

AB	PAR PHARMACEUTICAL	250MG		N70431 001 FEB 28, 1986

VANCOMYCIN HYDROCHLORIDE (PAGE 3-220)

CAPSULE; ORAL
VANCOCIN HCL

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

VANCOMYCIN HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION

VANCOCIN HCL

AP	ELI LILLY	EQ 500MG BASE/VIAL	N60180 001
AP		EQ 500MG BASE/VIAL*	N62476 001 MAR 15, 1986
		EQ 1GM BASE/VIAL*	N62476 002 MAR 21, 1986
		EQ 1GM BASE/VIAL*	N60180 002 MAR 21, 1986

VANCOLED

AP	LEDERLE PARENTERALS	EQ 500MG BASE/VIAL*	N62682 001 JUL 22, 1986

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION

VERAPAMIL HCL

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

TABLET; ORAL

VERAPAMIL HCL

AB	BARR LABORATORIES	80MG*	N70482 001 SEP 24, 1986 : SEP 23, 1986
AB		120MG*	N70483 001 SEP 24, 1986 : SEP 23, 1986
AB	CHELSEA LABORATORIES	80MG*	N70421 001 SEP 24, 1986 : SEP 17, 1986
AB		120MG*	N70422 001 SEP 24, 1986 : SEP 17, 1986
AB	DANBURY PHARMACAL	80MG*	N70855 001 SEP 24, 1986 : SEP 23, 1986
AB		120MG*	N70856 001 SEP 24, 1986 : SEP 23, 1986
AB	PARKE-DAVIS/W-L	80MG*	N70340 001 SEP 24, 1986 : AUG 20, 1986
AB		120MG*	N70341 001 SEP 24, 1986 : AUG 20, 1986
AB	PUREPAC/KALIPHARMA	80MG*	N71019 001 SEP 24, 1986 : SEP 23, 1986
AB		120MG*	N70468 001 SEP 24, 1986 : SEP 23, 1986

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

TABLET; ORAL

VERAPAMIL HCL

AB	NATSON LABS	80MG*	N70995 001 OCT 01, 1986
AB		80MG*	N71366 001 OCT 01, 1986
AB		120MG*	N70994 001 OCT 01, 1986
AB		120MG*	N71367 001 OCT 01, 1986

VINBLASTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION

VELBAN

AP	ELI LILLY	10MG/VIAL	N12665 001

VINBLASTINE SULFATE

AP	LYPHOMED	10MG/VIAL*	N89011 001 NOV 18, 1985
AP	QUAD PHARMS	10MG/VIAL*	N89365 001 AUG 07, 1986

VINCRISTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION

ONCOVIN

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

VINCRISTINE SULFATE

AP	LYPHOMED	1MG/ML*	N70411 001 SEP 10, 1986
AP	QUAD PHARMS	1MG/ML*	N70777 001 APR 29, 1986
AP		1MG/ML*	N70778 001 MAY 01, 1986

WARFARIN SODIUM (PAGE 3-221)

TABLET; ORAL

COUMADIN

AB	DUPONT PHARMS/DUPONT	2.5MG	N09218 018

WARFARIN SODIUM

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

ZINC CHLORIDE (PAGE 3-223)

INJECTABLE; INJECTION
ZINC CHLORIDE IN PLASTIC CONTAINER
ABBOTT LABORATORIES EQ 1MG ZINC/ML N19559 001
JUN 26, 1986

BACITRACIN ZINC; POLYMYXIN B SULFATE (PAGE 3-224)

AEROSOL; TOPICAL
- LANABIOTIC
  - COMBE — 500 UNITS/GM; 5,000 UNITS/GM — N50598 001 — SEP 22, 1986

CHLOR EXIDINE GLUCONATE (PAGE 3-224)

SOLUTION; TOPICAL
- CIDA-STAT
  - HUNTINGTON LABS — 2% — N19258 001 — JUL 22, 1986
- CHG SCRUB
  - HUNTINGTON LABS — 4% — N19258 002 — JUL 22, 1986
- EXIDINE
  - XTTRIUM LABS — 2% — N19422 001 — DEC 17, 1985
  - 2.5% — N19421 001 — DEC 17, 1985
- STERI-STAT
  - MEDICAL SYS RES — 4% — N70104 001 — JUL 24, 1986

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-225)

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

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-225)

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

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX (PAGE 3-225)

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

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-225)

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

DOXYLAMINE SUCCINATE (PAGE 3-225)

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

> ADD > **EPINEPHRINE** (PAGE 3-225)

> ADD > AEROSOL; INHALATION
> ADD > - BRONKAID MIST
> ADD > - WINTHROP-BREON/STERL — 0.25MG/INH — N16803 001
> ADD > - EPINEPHRINE MIST
> ADD > - NATL PHARM MFG/BARRE — 0.2MG/INH — N87907 001 — MAY 23, 1984
> ADD > - PRIMATENE MIST
> ADD > - WHITEHALL LABS/AMHO — 0.2MG/INH — N16126 001

> ADD > **EPINEPHRINE BITARTRATE** (PAGE 3-225)

> ADD > AEROSOL; INHALATION
> ADD > - BRONITIN MIST
> ADD > - WHITEHALL LABS/AMHO — 0.3MG/INH — N16126 002
> ADD > - MEDIHALER EPI
> ADD > - RIKER LABS/3M — 0.3MG/INH — N10374 003

IBUPROFEN (PAGE 3-225)

TABLET; ORAL

IBUPROFEN			
BARR LABORATORIES	200MG		N70493 001
		SEP 24, 1986 :	DEC 24, 1985
	200MG		N70908 001
			SEP 26, 1986
	200MG		N71462 001
			OCT 02, 1986
CHELSEA LABORATORIES	200MG		N70605 001
		SEP 24, 1986 :	MAY 07, 1986
CORD LABORATORIES	200MG		N70733 001
		SEP 24, 1986 :	SEP 19, 1986
DANBURY PHARMACAL	200MG		N70435 001
		SEP 24, 1986 :	MAR 05, 1986
OHM LABORATORIES	200MG		N71163 001
		SEP 24, 1986 :	JUL 15, 1986
PAR PHARMACEUTICAL	200MG		N70481 001
		SEP 24, 1986 :	OCT 18, 1985
PURPEC/KALIPHARMA	200MG		N71122 001
			OCT 03, 1986
MEDIPREN			
MCNEIL CONSUMER PROD	200MG		N70475 001
		SEP 24, 1986 :	FEB 06, 1986
	200MG		N71215 001
		SEP 24, 1986 :	JUN 26, 1986
PROFEN			
PRIVATE FORMULATIONS	200MG		N71265 001
			OCT 15, 1986

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

INJECTABLE; INJECTION

NOVOLIN 70/30		
SQUIBB/NOVO	30 UNITS/ML;70 UNITS/ML	N19441 001
		JUL 11, 1986

INSULIN, PURIFIED PORK (PAGE 3-227)

INJECTABLE; INJECTION

/INSULIN NORDISK QUICK (PORK)/		
VELOSULIN		
NORDISK	100 UNITS/ML	N18193 001

INSULIN SUSPENSION, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION

HUMULIN BR		
ELI LILLY	100 UNITS/ML	N19529 001
		APR 28, 1986

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

INJECTABLE; INJECTION

HUMULIN N		
ELI LILLY	100 UNITS/ML	N18781 001
		OCT 28, 1982

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

INJECTABLE; INJECTION

INSULATARD NPH HUMAN		
NORDISK USA	100 UNITS/ML	N19449 001
		MAY 30, 1986

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

INJECTABLE; INJECTION

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

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

INJECTABLE; INJECTION

VELOSULIN HUMAN		
NORDISK USA	100 UNITS/ML	N19450 001
		MAY 30, 1986

OXYMETAZOLINE HYDROCHLORIDE (PAGE 3-228)

SOLUTION/DROPS; OPHTHALMIC

OCUCLEAR		
SCHERING	0.025%	N18471 001
		MAY 30, 1986

POVIDONE-IODINE (PAGE 3-228)

SPONGE; TOPICAL

POVIDONE-IODINE		
PARKE-DAVIS/DESERET	20%	N19240 001
		NOV 29, 1985

PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-228)

CAPSULE, CONTROLLED RELEASE; ORAL

/SUDAFED S.A./		
SUDAFED 12 HOUR		

PYRITHIONE ZINC (PAGE 3-228)

LOTION; TOPICAL
HEAD & SHOULDERS CONDITIONER

PROCTER AND GAMBLE	0.3%*	N19412 001 MAR 10, 1986
	0.3%*	N19412 002 MAR 10, 1986
	0.3%*	N19412 003 MAR 10, 1986
	0.3%*	N19412 004 MAR 10, 1986

SODIUM MONOFLUOROPHOSPHATE (PAGE 3-229)

GEL; DENTAL
EXTRA-STRENGTH AIM

LEVER BROTHERS	1.2%*	N19518 001 AUG 06, 1986

NO SEPTEMBER 1985 - NOVEMBER 1986 APPROVALS

C. APPENDICES

1. Orphan Drug Products with Exclusive Approval

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

3. Biopharmaceutic Guidance Availability List

4. ANDA Suitability Petitions

5. Exclusivity Terms

6. Prescription and OTC Drug Product Patent and Exclusivity Data

APPENDIX 1

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

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

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

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

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

APPENDIX 1

BIOLOGICAL PRODUCTS

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

APPENDIX 1

DRUG PRODUCTS

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

(continued)

*Refer to Appendix I narrative

APPENDIX 1

DRUG PRODUCTS

(continued)

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

APPENDIX 2

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

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

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

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

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

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

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

Aminophylline
Tablet; Oral
100mg
200mg

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

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

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

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

Aspirin; Carisoprodol
Tablet; Oral
325mg; 200mg

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

Aspirin; Meprobamate
Tablet; Oral
325mg; 200mg

Aspirin; Methocarbamol
Tablet; Oral
325mg; 200mg

Chlorothiazide
Tablet; Oral
250mg

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

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

APPENDIX 3

BIOPHARMACEUTIC GUIDANCE AVAILABILITY LIST

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

Name of Drug	Date	Revised Date
Acetohexamide	Nov 15, 1985	
Allopurinol	Jul 15, 1985	
Amiloride Hydrochloride	Mar 29, 1985	
Aminophylline Suppositories	Jul 05, 1983	
Amitriptyline Hydrochloride	Jul 05, 1983	
Anticholinergic Drugs (Controlled Release)	Nov 07, 1980	
Baclofen	May 05, 1986	
Carbamazepine	Dec 05, 1984	Aug 04, 1986
Cefadroxil	Oct 07, 1986	
Cephradine (Capsule and Suspension)	Sep 10, 1986	
Cephalexin (Tablet and Capsule)	Aug 13, 1986	Oct 27, 1986
Chlordiazepoxide Hydrochloride	Jul 05, 1983	
Chlorpropamide	Jul 05, 1983	
Chlorthalidone	Jul 05, 1983	
Clofibrate	Apr 07, 1986	
Clonidine Hydrochloride	Dec 05, 1984	
Clorazepate Dipotassium	Mar 10, 1986	
Diazepam (revised)	Jul 08, 1985	
Dicyclomine Hydrochloride	Aug 10, 1984	
Dipyridamole	Jul 05, 1983	

(continued)

APPENDIX 3

(continued)

Name of Drug	Date	Revised Date
Disopyramide Phosphate	Jul 09, 1985	
Dissolution Testing (General)	Apr 19, 1985	
Doxepin Hydrochloride	Apr 02, 1985	Oct 09, 1986
Erythromycin	Apr 05, 1977	
Flurazepam	Oct 15, 1985	
Hydrochlorothiazide	Jul 25, 1983	
Hydroxyzine Hydrochloride (Dissolution Only)	Jan 27, 1981	
Hydroxyzine Pamoate	Jul 26, 1983	
Indomethacin	Apr 06, 1985	
Isosorbide Dinitrate	Jun 04, 1985	
Isosorbide Dinitrate (Controlled Release Products)	Sep 19, 1985	
Lorazepam	Dec 03, 1984	
Meclofenamate Sodium	Nov 12, 1986	
Methylprednisolone	Jun 12, 1986	
Methyltestosterone	Nov 16, 1979	
Metoclopramide	Dec 27, 1984	
Minoxidil	Apr 02, 1986	
Nitrofurantoin (Macrocrystalline)	Oct 29, 1985	
Phentermine Hydrochloride (Dissolution)	Nov 21, 1980	
Phentermine Hydrochloride (Slow Dissolving; Dissolution)	Nov 21, 1980	
Phenylbutazone & Oxyphenbutazone	Jul 26, 1983	
Prednisone (Dissolution Only)	Jul 10, 1985	
Probenecid	Jul 26, 1983	
Procainamide	Jul 25, 1983	
Propranolol	May 19, 1984	
Propylthiouracil	Aug 13, 1986	

(continued)

APPENDIX 3

(continued)

Name of Drug	Date	Revised Date
Quinidine Gluconate (Controlled Release)	Jun 15, 1981	
Spironolactone	Jul 25, 1983	
Sulfinpyrazone	Jul 15, 1983	
Temazepam	Aug 1985	
Theophylline (Controlled Release)	Apr 1984	
Theophylline (Immediate Release)	Nov 02, 1983	
Tolazamide	Aug 22, 1984	
Tolbutamide	Jan 1982	
Trazodone	Nov 15, 1985	Apr 30, 1986
Trimipramine	Nov 03, 1986	
Verapamil	Jul 1985	

APPENDIX 4

ANDA SUITABILITY PETITIONS

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

I. Petitions Approved

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Capsule; Oral	500mg 30mg	84 P-0228/CP	McNeil Pharm	New Dosage Form New Strength	Approved Jun 02, 1986
Acetaminophen; Codeine Phosphate Capsule; Oral	500mg 60mg	84 P-0228/CP	McNeil Pharm	New Dosage Form New Strength	Approved Jun 02, 1986
Acetaminophen; Codeine Phosphate Capsule; Oral	650mg 15mg	86 P-0200/CP	Mikart, Inc	New Strength New Dosage Form	Approved Oct 3, 1986
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	300mg 30mg	85 P-0543/CP	Softan	New Dosage Form	Approved Mar 18, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	500mg 7.5mg	85 P-0543/ CP0002	Softan	New Dosage Form New Strength	Approved Mar 19, 1986
Acetaminophen; Codeine Phosphate Soft Gelatin Capsule; Oral	500mg 15mg	85 P-0543/ CP0002	Softan	New Dosage Form New Strength	Approved Mar 19, 1986
Acetaminophen; Codeine Phosphate Elixir; Oral	160mg/5ml 6mg/5ml	86 P-0133/CP	Kleinfeld, Kaplan and Becker	New Strength	Approved May 21, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 15mg	86 P-0161/CP	Roxane Laboratories	New Strength	Approved May 8, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 30mg	86 P-0161/CP	Roxane Laboratories	New Strength	Approved May 8, 1986
Acetaminophen; Codeine Phosphate Tablet; Oral	500mg 60mg	86 P-0161/CP	Roxane Laboratories	New Strength	Approved May 8, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen; Codeine Phosphate Tablet; Oral	650mg 15mg	86 P-0200/CP	Mikart, Inc	New Strength	Approved Oct 3, 1986
Acetaminophen; Hydrocodone Bitartrate Solution; Oral	500mg/15ml 5mg/15ml	84 P-0391/CP	UAD Laboratories	New Dosage Form	Approved Jul 2, 1985
Acetaminophen; Oxycodone Hydrochloride Solution; Oral	325mg/5ml 5mg/5ml	85 P-0085/CP	Roxane Laboratories	New Dosage Form	Approved Aug 23, 1985
Acetaminophen; Oxycodone Hydrochloride Soft Gelatin Capsule; Oral	500mg 5mg	85 P-0543/ CP0003	Softan	New Dosage Form	Approved Mar 18, 1986
Acetaminophen; Propoxyphene Hydrochloride Soft Gelatin Capsule; Oral	500mg 32mg	85 P-0581/CP	Softan	New Dosage Form New Strength	Approved Mar 18, 1986
Acetaminophen Suppository; Rectal	80mg	85 P-0403/CP	Upsher-Smith Labs	New Dosage Form (Pediatric)	Approved Oct 16, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Aminocaproic Acid Injectable; Injection	500mg/ml 10ml/vial	85 P-0308/CP	Abbott Laboratories	New Strength	Approved Feb 12, 1986
Aminophylline Injectable; Injection	10mg/ml 10ml/vial	85 P-0459/CP	Abbott Laboratories	New Strength	Approved Feb 12, 1986
Aminophylline Injectable; Injection	50mg/ml 20ml/vial	85 P-0459/CP	Abbott Laboratories	New Strength	Approved Feb 12, 1986
Aspirin; Caffeine; Dihydrocodeine Bitartrate Tablet; Oral	356.4mg 30mg 16mg	86 P-0359/CP	Central Pharms	New Dosage Form	Approved Sep 29, 1986
Azatadine Maleate; Phenylpropanolamine Hydrochloride Sustained Release Capsule; Oral	1mg 75mg	85 P-0492/CP	SK&F Laboratories	New Combination New Dosage Form	Approved Jan 28, 1986
Benztropine Mesylate Syrup; Oral	0.5mg/5ml	85 P-0423/CP	RIM Consulting	New Dosage Form	Approved Oct 16, 1985
Bretylium Tosylate Injectable; Injection	100mg/ml	86 P-0157/CP	Lyphomed	New Strength	Approved May 8, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Brompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	12mg 120mg	85 P-0095/CP	UAD Laboratories	New Combination New Dosage Form	Approved Dec 13, 1985
Cholestyramine Tablet, Chewable; Oral	Eq 4gm Resin	86 P-0123/CP	Parke-Davis Labs/W-L	New Dosage Form	Approved Jun 20, 1986
Chlorpheniramine Maleate; Phenylpropanolamine Hydrochloride Controlled-release Capsule; Oral	10mg 75mg	85 P-0149/CP	Dura Pharmaceuticals	New Strength	Approved Dec 13, 1985
Chlorhexidine Gluconate Solution; Topical	1.5%	84 P-0417/CP	Parke Davis	New Strength	Approved Sep 18, 1985
Cisplatin Injectable, Injection	100mg/vial	86 P-0395/CP	Ben Venue Labs	New Strength	Approved Dec 8, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Codeine Phosphate; Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Syrup; Oral	10mg/5ml 1mg/5ml 12.5mg/5ml	85 P-0269/CP	Bock Pharmacal	New Combination	Approved Dec 6, 1985
Cytarabine Injectable; Injection	20mg/ml 5ml/Vial	86 P-0130/CP	Quad Pharms	New Dosage Form	Approved Aug 21, 1986
Cytarabine Injectable; Injection	20mg/ml 25ml/vial	86 P-0130/CP	Quad Pharms	New Dosage Form	Approved Aug 21, 1986
Dacarbazine Injectable; Injection	500mg/Vial	86 P-0300/CP	Quad Pharms	New Strength	Approved Aug 15, 1986
Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Time Release Capsule; Oral	6mg 75mg	85 P-0238/CP0002	Bock Pharmacal	New Combination	Approved Dec 13, 1985
Dexbrompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/CP	Central Pharms	New Combination New Dosage Form	Approved Dec 13, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Dexbrompheniramine Maleate; Pseudoephedrine Sulfate Sustained Release Capsule; Oral	6mg 120mg	85 P-0140/ CP0002	Central Pharms	New Dosage Form	Approved Jan 22, 1986
Diazepam Solution; Oral	5mg/5ml	85 P-0090/CP	Roxane Laboratories	New Dosage Form	Approved Sep 19, 1985
Diazepam Syrup; Oral	2mg/5ml	85 P-0499/CP	Carolina Med Prods	New Dosage Form	Approved Feb 28, 1986
Diazepam Intensol Solution (Concentrate); Oral	5mg/ml	85 P-0566/CP	Roxane Laboratories	New Dosage Form	Approved Mar 18, 1986
Diphenhydramine Hydrochloride Concentrate; Oral	50mg/ml	84 P-0174/CP	Roxane Laboratories	New Strength	Approved Sep 11, 1985
Disopyramide Phosphate Tablet, Controlled Release; Oral	200mg 300mg	84 N-0116/CP	Biocraft Labs	New Dosage Form New Strength	Approved Jun 03, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Disulfiram Suspension; Oral	500mg/30ml	85 P-0215/CP	Paddock Laboratories	New Dosage Form	Approved Oct 8, 1985
Estradiol Tablet; Oral	0.5mg	84 P-0308/CP	Key Pharmaceuticals	New Strength	Approved Mar 24, 1986
Floxuridine Injectable; Injection	500mg/5ml	86 P-0242/CP	Quad Pharms	New Dosage Form	Approved Aug 15, 1986
Fluorouracil Injectable; Injection	25mg/ml	85 P-0208/CP	Intl Pharm Prods	New Strength	Approved Oct 8, 1985
Fluorouracil Injectable; Injection	50mg/ml (100ml/vial)	85 P-0221/CP	LyphoMed	New Strength	Approved Feb 18, 1986
Fluorouracil Injectable; Injection	50mg/20ml	86 P-0080/CP	Ben Venue Labs	New Strength	Approved Apr 2, 1986
Flurazepam Concentrate; Oral	30mg/ml	85 P-0081/CP	Roxane Laboratories	New Dosage Form	Approved Jul 10, 1985
Flurazepam Hydrochloride Solution; Oral	15mg/5ml	85 P-0091/CP	Roxane Laboratories	New Dosage Form	Approved Oct 25, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Furosemide Solution; Oral	40mg/5ml	85 P-0106/ CP0002	Roxane Laboratories	New Strength	Approved Sep 19, 1985
Furosemide Concentrate; Oral	80mg/ml	85 P-0106/CP	Roxane Laboratories	New Strength	Approved Sep 19, 1985
Glucagon Injectable; Injection	Eq 2mg Base/Amp	86 P-0411/CP	King and Spaulding	New Strength	Approved Oct 30, 1986
Haloperidol Solution; Oral	2mg/5ml	85 P-0076/ CP0002	Roxane Laboratories	New Strength	Approved Mar 26, 1986
Haloperidol Lactate Intensol Concentrate; Oral	Eq 5mg Base/ml	85 P-0076/CP	Roxane Laboratories	New Strength	Approved Dec 8, 1986
Haloperidol Solution; Oral	5mg/5ml	85 P-0080/CP	Roxane Laboratories	New Strength	Approved Sep 19, 1985
Hydralazine Hydrochloride Solution; Oral	25mg/5ml	85 P-0074/CP	Roxane Laboratories	New Dosage Form	Approved Jul 3, 1985
Ibuprofen Capsule; Oral	200mg	84 P-0383/CP	Sterling Drug	New Dosage Form	Approved Jun 25, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Ibuprofen Soft Gelatin Capsule; Oral	300mg 400mg 600mg	85 P-0563/CP	Softan	New Dosage Form	Approved Mar 19, 1986
Indomethacin Suspension; Oral	25mg/5ml	85 P-0077/ CP0002	Roxane Laboratories	New Dosage Form	Approved Jul 19, 1985
Isoniazid Concentrate; Oral	50mg/ml	85 P-0468/CP	Carolina Med Prods	New Strength	Approved Dec 13, 1985
Ketoconazole Suspension; Oral	20mg/ml	85 P-0147/CP	Janssen Pharma	New Dosage Form	Approved Sep 27, 1985
Leucovorin Calcium Tablet; Oral	15mg	85 P-0487/CP	Lederle Labs/AM Cyan	New Strength	Approved Jan 28, 1986
Lorazepam Oral; Solution	1mg/5ml	86 P-0292/CP	Roxane Laboratories	New Dosage Form	Approved Oct 15, 1986
Lorazepam Solution (Concentrate); Oral	2mg/ml	86 P-0291/CP	Roxane Laboratories	New Dosage Form	Approved Oct 15, 1986
Meperidine Hydrochloride Concentrate; Oral	100mg/ml	84 P-0175/CP	Roxane Laboratories	New Strength	Approved Jun 7, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Metaproterenol Sulfate Solution; Inhalation	10mg/2.5ml	85 P-0509/CP	Armour Pharm	New Strength	Approved Feb 28, 1986
Metaproterenol Sulfate Solution; Inhalation	10mg/3ml	85 P-0429/ CP0002	Dey Laboratories	New Strength	Approved Feb 28, 1986
Metaproterenol Sulfate Solution; Inhalation	15mg/3ml	85 P-0429/CP	Dey Laboratories	New Strength	Approved Feb 28, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 20ml/vial	86 P-0036/CP	AM Critcal Care/AHS	New Strength	Approved Mar 18, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 50ml/vial	85 P-0545/CP	Lyphomed	New Strength	Approved Feb 28, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 50ml/vial	85 P-0540/CP	Quad Pharms	New Strength	Approved Feb 28, 1986
Metoclopramide Hydrochloride Injectable; Injection	5mg/ml 100ml/vial	85 P-0540/CP	Quad Pharms	New Strength	Approved Feb 28, 1986
Methyldopate Hydrochloride Injectable; Injection	50mg/ml 10ml/vial	85 P-0404/CP	AM Critical Care/AHS	New Strength	Approved Oct 25, 1985
Methyltestosterone Capsule; Oral	25mg	85 P-0067/CP	Star Pharmaceuticals	New Dosage Form	Approved Aug 23, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Miconazole Nitrate Cream; Vaginal	4%	84 P-0398/CP	Ortho Pharmaceutical	New Strength	Approved Mar 31, 1986
Naloxone Hydrochloride Injectable; Injection	1mg/ml 5ml/vial	86 P-0079/CP	AM Critical Care/AHS	New Strength	Approved May 7, 1986
Naloxone Hydrochloride Injectable; Injection	1mg/ml 10ml/vial	86 P-0079/CP	AM Critical Care/AHS	New Strength	Approved May 7, 1986
Nitroglycerin Injectable; Injection	5mg/ml	86 P-0025/CP	Lyphomed	New Strength	Approved Apr 1, 1986
Nitroglycerin Injectable; Injection	10mg/ml	85 P-0134/CP	Marion Laboratories	New Strength	Approved Sep 19, 1985
Nitroglycerin in 5% Dextrose Injectable; Injection	10mg/100ml (500ml Container)	86 P-0099/CP	Abbott Laboratories	New Strength	Approved Apr 1, 1986
Nitroglycerin in 5% Dextrose Injectable; Injection	20mg/100ml (250ml Container)	86 P-0099/ CP0002	Abbott Laboratories	New Strength	Approved Apr 1, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Nitroglycerin in 5% Dextrose Injectable; Injection	40mg/100ml (250ml and 500ml Containers)	86 P-0099/ CP0003	Abbott Laboratories	New Strength	Approved Apr 1, 1986
Prednisolone Syrup; Oral	5mg/5ml	86 P-0399/CP	Muro Pharmaceutical	New Strength	Approved Dec 8, 1986
Probucol Tablet; Oral	500mg	85 P-0337/CP	Merrell Dow/Dow Chem	New Strength	Approved Oct 25, 1985
Procainamide Hydrochloride Tablet; Oral	375mg	85 P-0125/CP	Key Pharmaceuticals	New Strength	Approved Sep 19, 1985
Propranolol Hydrochloride Capsule; Oral	10mg 20mg 40mg 60mg 80mg 90mg	86 P-0045/CP	Nutripharm Labs	New Dosage Form	Approved Mar 19, 1986
Propranolol Hydrochloride Solution; Oral	40mg/5ml	85 P-0073/CP	Roxane Laborataories	New Dosage Form	Approved Jul 8, 1985
Propranolol Hydrochloride Concentrate; Oral	80mg/ml	85 P-0073/ CP0002	Roxane Laboratories	New Dosage Form	Approved Jul 19, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Propranolol Hydrochloride Solution; Oral	20mg/5ml	85 P-0073/ CP0003	Roxane Laboratories	New Dosage Form	Approved Sep 24, 1985
Propranolol Hydrochloride Tablet, Constant-Release; Oral	160mg	85 P-0129/CP	Verex Laboratories	New Dosage Form	Approved Sep 25, 1985
Propranolol Hydrochloride Tablet, Controlled Release; Oral	80mg 120mg 160mg	85 P-0197/CP	Forest Laboratories	New Dosage Form	Approved Sep 27, 1985
Pyridostigmine Bromide Tablet; Oral	30mg	85 P-0412/CP	Kali-Duphar Labs	New Strength	Approved Jan 22, 1986
Ritodrine Hydrochloride in Dextrose 5% Injectable; Injection	30mg/100ml 500ml Container	86 P-0100/CP	Abbott Laboratories	New Strength	Approved May 7, 1986
Scopolamine Transdermal System/24 Hour Film, Controlled Release; Percutaneous	1mg	85 P-0168/CP	Ciba Consumer Pharms	New Strength (Dosing Interval)	Approved Sep 27, 1985
Spironolactone Syrup; Oral	25mg/5ml	85 P-0510/CP	Carolina Med Prods	New Dosage Form	Approved Jan 22, 1986

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Spironolactone Oral; Injection	25mg/5ml	86 P-0055/CP	Carolina Med Prods	New Dosage Form	Approved Mar 28, 1986
Theophylline Capsule; Oral	150mg 300mg	85 P-0175/CP	Mead Johnson/B-M	New Strength	Approved Oct 8, 1985
Theophylline Tablet Controlled-release; Oral	600mg	85 P-0580/CP	Purdue Frederick	New Strength	Approved Oct 15, 1986
Thiothixene Hydrochloride Solution; Oral	5mg/5ml	86 P-0178/CP	Ellis Pharmaceutical	New Strength	Approved Jun 04, 1986
Triamcinolone Acetonide Cream; Topcial	0.05%	86 P-0360/CP	Carolina Med Prods	New Strength	Approved Oct 15, 1986
Triamcinolone Acetonide Ointment; Topcial	0.05%	86 P-0360/CP	Carolina Med Prods	New Strength	Approved Oct 15, 1986
Vinblastine Sulfate Injectable; Injection	1mg/ml	86 P-0056/CP	Quad Pharms	New Dosage Form	Approved Mar 28, 1986
Vincristine Sulfate Injectable; Injection	2mg/vial	85 P-0016/CP	Bristol Labs/B-M	New Dosage Form	Approved Nov 8, 1985
Xenon XE 133 Gas; Inhalation	150mCi/vial 250mCi/vial	86 P-0041/CP	Medi Nuculear Corp, Inc	New Strength	Approved Oct 15, 1986

APPENDIX 4

II. Petitions Denied

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	650mg 10mg	85 P-0015/CP	Applied Labs	New Strength	Denied Nov 7, 1985
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	750mg 7.5mg	85 P-0169/CP	Knoll Pharmaceutical	New Strength	Denied Nov 7, 1985
Aminocaproic Acid Injectable; Injection	500mg/ml	85 P-0064/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Aminophylline Injectable; Injection	10mg/ml	85 P-0066/CP	Abbott Laboratories	New Strength	Denied May 3, 1985
Aminophylline Injectable; Injection	50mg/ml	85 P-0066/CP	Abbott Laboratories	New Strength	Denied May 3, 1985
5-Aminosalicylic Acid Suppository; Rectal	500mg	84 P-0425/CP	Reid-Rowell	New Ingredient	Denied Jun 05, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Cholecalciferol Capsule; Oral	1.25mg	84 P-0161/CP	Pharmacaps	New Active Ingredient	Denied Feb 13, 1986
Codeine Phosphate; Ibuprofen Capsule; Oral	30mg 200mg	84 P-0388/CP	McNeil Pharm	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Capsule; Oral	60mg 200mg	84 P-0388/CP	McNeil Pharm	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Tablet; Oral	30mg 200mg	84 P-0388/CP	McNeil Pharm	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Tablet; Oral	60mg 200mg	84 P-0388/CP	McNeil Pharm	New Combination	Denied Sep 16, 1985
Choline Magnesium Trisalicylate Codeine Phosphate Tablet; Oral	500mg 30mg	85 P-0142/CP	Purdue Frederick	New Combination	Denied Jul 21, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Choline Magnesium Trisalicylate; Codeine Phosphate Tablet; Oral	500mg 60mg	85 P-0142/CP	Purdue Frederick	New Combination	Denied Jul 21, 1986
Dextromethorphan Hydrobromide Tablet, Controlled Release; Oral	60mg	85 P-0135/CP	Ciba Consumer Pharms	New Salt New Ingredient	Denied Jul 17, 1986
Diatrizoate Meglumine; Lidocaine Hydrochloride Injectable; Injection	60% 1.5mg/ml	84 P-0325/CP	Cook Imaging	New Combination	Denied Sep 3, 1985
Diazepam Intensol Concentrate; Oral	10mg/ml	85 P-0075/CP	Roxane Laboratories	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	Ortho Pharmaceutical	New Strength (Dose Schedule)	Denied Sep 3, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Fluphenazine Hydrochloride Injectable; Injection	5mg/ml	85 P-0019/CP	ER Squibb and Sons	New Strength	Denied Oct 25, 1985
Heparin Sodium Injectable; Injection	2000 Units/ml	85 P-0065/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Heparin Sodium Injectable; Injection	4000 Units/ml	85 P-0065/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release; Oral	50mg 80mg 75mg	85 P-0571/CP	Ayerst Labs/AMHO	New Combination	Denied May 16, 1986
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release; Oral	50mg 120mg 75mg	85 P-0571/CP	Ayerst Labs/AMHO	New Combination	Denied May 16, 1986
Hydrochlorothiazide; Propranolol Hydrochloride; Triamterene Capsule, Controlled Release;	50mg 160mg 75mg	85 P-0571/CP	Ayerst Labs/AMHO	New Combination	Denied May 16, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Hydrocortisone Acetate Suppository; Rectal	1%	85 P-0088/CP	Parke-Davis Labs/W-L	New Dosage Form New Route of Administration New Strength New Ingredient	Denied Sep 16, 1986
Ibuprofen; Oxycodone Hydrochloride Capsule; Oral Oral	200mg 5mg	85 P-0141/CP	Dupont Pharms/Dupont	New Combination	Denied Sep 27, 1985
Ibuprofen; Oxycodone Hydrochloride Tablet; Oral	200mg 5mg	85 P-0141/CP	Dupont Pharms/Dupont	New Combination	Denied Sep 27, 1985
Indomethacin Tablet; Oral	25mg	85 P-0025/CP	Verex Laboratories	New Dosage Form	Denied Mar 31, 1986
Indomethacin Tablet; Oral	50mg	85 P-0025/CP	Verex Laboratories	New Dosage Form	Denied Mar 31, 1986
Indomethacin Intensol Solution (Concentrate); Oral	50mg/ml	85 P-0077/CP	Roxane Laboratories	New Dosage Form New Strength	Denied Apr 7, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Indomethacin Tablet, Constant Release; Oral	75mg	85 P-0026/CP	Verex Laboratories	New Dosage Form	Denied Sep 16, 1985
Indomethacin Controlled-release Tablet; Oral	75mg	85 P-0180/CP	Forest Laboratories	New Dosage Form	Denied Apr 7, 1986
Methocarbamol Acetaminophen Tablet; Oral	400mg 325mg	85 P-0102/CP	McNeil Pharm	New Combination	Denied Jun 24, 1986
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml 50ml/vial	86 P-0015/CP	Intl Medication Sys	New Strength	Denied Apr 25, 1986
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml 75ml/vial	86 P-0015/CP	Intl Medication Sys	New Strength	Denied Apr 25, 1986
Metoclopramide Hydrochloride Injectable; Injection	1mg/ml 100ml/vial	86 P-0015/CP	Intl Medication Sys	New Strength	Denied Apr 25, 1986
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0062/CP	Abbott Laboratories	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0457/CP	Abbott Laboratories	New Strength	Denied Apr 18, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form; Route	Strength (Container Size)	Docket Number	Petitioner	Reason for Petition	Status
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0062/ CP0002	Abbott Laboratories	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0457/ CP0002	Abbott Laboratories	New Strength	Denied Apr 18, 1986
Metronidazole Sponge; Vaginal	50-125mg/ Sponge	85 P-0117/CP	VLI	New Dosage Form	Denied Oct 8, 1985
Nitroglycerin Transdermal System	None Given	84 P-0302/CP	Key Pharmaceuticals	New Dosage Form (New Matrix)	Denied Jul 29, 1985
Phenylephrine Hydrochloride; Sulfathiazole Nasal Suspension; Topical	0.5% 5%	85 P-0205/CP	Tanya W Ross	New Dosage Form New Combination	Denied Nov 14, 1985
Pseudoephedrine Polisterex Controlled Release Capsule; Oral	60mg	85 P-0334/CP	Pennwalt Pharm	New Salt New Ingredient	Denied Mar 19, 1986
Temazepam Soft Gelatin Capsule; Oral	10mg 20mg	85 P-0016/CP	Wyeth/AMHO	New Strength	Denied Sep 29, 1986

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 5

(continued)

NEW 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
D-12	BEDTIME DOSING OF 800MG FOR TREATMENT

NEW INDICATION

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

(continued)

APPENDIX 5

(continued)

NEW INDICATION

I-17	PITUITARY TUMORS
I-18	POSTMENOPAUSAL OSTEOPOROSIS
I-19	ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
I-20	CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE
I-21	ACUTE OTITIS MEDIA
I-22	EXERCISE INDUCED BRONCHOSPASMS
I-23	MYOCARDIAL INFARCTION OR STROKE
I-24	COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL
I-25	BLASTOMYCOSES DERMATITIDES
I-26	PEDIATRIC SUBARACHNOID VASCULAR
I-27	PETRIELLIDIUM BOYDII INFECTION
I-28	HEREDITARY ANGIOEDEMA
I-29	INTRACORONARY USE
I-30	PEDIATRIC USE
I-31	DIRECT ISOTOPIC CYSTOGRAPHY
I-32	POSTPARTUM HEMORRHAGE
I-33	USE IN METHODONE INDUCED RESPIRATORY DEPRESSION
I-34	PROLACTIN SECRETING ADENOMAS
I-35	ANGINA PECTORIS DUE TO CORONARY ATHEROSCLEROSIS
I-36	ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
I-37	SPINAL ANESTHESIA
I-38	PATIENT PREOPERATIVE SKIN PREPARATION
I-39	ADJUVANT WITH CHEMOTHERAPY FOR TREATMENT OF BREAST CANCER FOLLOWING MASTECTOMY
I-40	ANTIDOTE FOR ACETAMINOPHEN OVERDOSE

(continued)

APPENDIX 5

(continued)

NEW INDICATION

I-41	MANAGEMENT OF HYPOCALCEMIA AND RESULTANT METABOLIC BONE DISEASE IN RENAL DIALYSIS PATIENTS
I-42	MAINTENANCE THERAPY AT REDUCED DOSE FOLLOWING HEALING OF ACUTE DUODENAL ULCER
I-43	TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE
I-44	TREATMENT OF SEVERE RECALCITRANT DERMATOPHYTE INFECTIONS
I-45	ACCELERATE BARIUM TRANSIT THEREBY DECREASING TIME AND EXTENT OF RADIATION TO INTESTINAL TRACT
I-46	TREATMENT OF SMALL CELL LUNG CANCER IN COMBINATION WITH OTHER APPROVED CHEMOTHERAPEUTIC DRUGS
I-47	USE IN BALANCED ANESTHESIA
I-48	MANAGEMENT OF FAMILIAL OR HEREDITARY ESSENTIAL TREMOR

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 1985 - NOVEMBER 1986 ACTIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	/12142/001/	/4537883/	/AUG/27,/2002/		
	/12142/002/	/4537883/	/AUG/27,/2002/		
	/12142/003/	/4537883/	/AUG/27,/2002/		
	/12142/004/	/4537883/	/AUG/27,/2002/		
	/12142/005/	/4537883/	/AUG/27,/2002/		
	12142 006	4537883	AUG 27, 2002		
	12142 007	4537883	AUG 27, 2002		
	12142 008	4537883	AUG 27, 2002		
	12142 009	4537883	AUG 27, 2002		
	12142 010	4537883	AUG 27, 2002		
	12365 005	4534973	AUG 13, 2002		
	12366 002	4534974	AUG 13, 2002		
	13601 001			I-40	JAN 31, 1988
	13601 002			I-40	JAN 31, 1988
> ADD >	14013 003	4619935	OCT 28, 2003		
	/14715/001/	/3428735/	/FEB/18,/1986/		
	14715 004	3428735	FEB 18, 1986		
	/16273/001/	/4324779/	/APR/13,/1999/		
	/16273/002/	/4324779/	/APR/13,/1999/		
	/16273/003/	/4324779/	/APR/13,/1999/		
	/16363/001/	/4324779/	/APR/13,/1999/		
	16418 001			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 002			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 003			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 004			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 009			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16418 010			D-7	OCT 31, 1989
				I-48	OCT 31, 1989
	16636 002			D-9	SEP 24, 1986
				D-10	
				D-11	
				I-33	
	16983 001			I-36	SEP 09, 1988

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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	3410565	DEC 31, 1985		
	3717647	FEB 20, 1990		
17613 001	3839573	OCT 01, 1991		
17619 001	3839573	OCT 01, 1991		
17668 001	4324779	APR 13, 1999		
17697 001			I-45	AUG 25, 1989
17717 001	3839573	OCT 01, 1991		
17760 001			NDF	SEP 04, 1988
17768 001	3855140	DEC 17, 1991	I-38	SEP 24, 1986
	3960745	DEC 17, 1991		
17785 001			NDF	MAR 07, 1989
17862 001	4536386	AUG 20, 2002	I-12	SEP 24, 1986
			I-13	SEP 24, 1986
			I-14	SEP 24, 1986
17862 002	4536386	AUG 20, 2002	I-12	SEP 24, 1986
			I-13	SEP 24, 1986
			I-14	SEP 24, 1986
17862 003	4536386	AUG 20, 2002	I-12	SEP 24, 1986
			I-13	SEP 24, 1986
			I-14	SEP 24, 1986
17920 005	3950333	APR 13, 1993	D-12	APR 30, 1989
	4024271	MAY 17, 1994		
17970 001	4536516	AUG 20, 2002	I-39	DEC 10, 1988
18024 001			I-47	OCT 23, 1989
18024 002			I-47	OCT 23, 1989
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
18063 005	3935267	JAN 27, 1993		
	3982021	SEP 21, 1993		
18147 002	RE29668	DEC 16, 1991		
	4100347	JUL 11, 1995		
	3927002	DEC 16, 1992		
18147 003	RE29668	DEC 16, 1991		
	4100347	JUL 11, 1995		
	3927002	DEC 16, 1992		
18154 001	3461461	MAY 07, 1985		
18154 003	3461461	MAY 07, 1985		
18155 001			ODE	OCT 03, 1991
18181 001	3839573	OCT 01, 1991		
18182 001	3839573	OCT 01, 1991		
18183 001	3839573	OCT 01, 1991		
18217 001	4035376	JUL 12, 1994	NCE	DEC 24, 1990
18230 001	3839573	OCT 01, 1991		
18240 001			I-35	SEP 04, 1988
18240 002			I-35	SEP 04, 1988
18257 001	4237068	NOV 09, 1998		
18257 002	4237068	NOV 09, 1998		
18401 001	3433791	MAR 18, 1986		
18423 001	3855140	DEC 17, 1991		
	3960745	DEC 17, 1991		
18470 001	4347242	JUN 30, 1998	NCE	OCT 31, 1991
18471 001			NDF	MAY 30, 1989
18482 001	3784684	JAN 08, 1991		
18482 002	3644627	FEB 22, 1989		
	3784684	JAN 08, 1991		
18489 001	RE31463	APR 12, 1994	NCE	OCT 31, 1991
18506 001	3410565	DEC 31, 1985		
	3717647	FEB 20, 1990		

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
18509 001			NP	AUG 07, 1988
18513 002			ODE	JUL 28, 1990
18533 001			I-44	JUN 30, 1989
18587 003	3658993	APR 25, 1989	NCE	SEP 07, 1992
18644 001	3819706	JUN 25, 1991	NCE	DEC 30, 1990
	3885046	MAY 20, 1992		
	4057323	MAR 26, 2002		
	4347257	AUG 31, 1999		
	4393078	JUL 12, 2000		
	4425363	JAN 10, 2001		
	4435449	MAR 06, 2001		
	4438138	MAR 20, 2001		
18644 002	3819706	JUN 25, 1991	NCE	DEC 30, 1990
	3885046	MAY 20, 1992		
	4057323	MAR 26, 2002		
	4347257	AUG 31, 1999		
	4393078	JUL 12, 2000		
	4425363	JAN 10, 2001		
	4435449	MAR 06, 2001		
	4438138	MAR 20, 2001		
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		
/18682/001/	/4062966/	/DEC/13/1994/	/NCE/	/SEP/24,/1986/
18682 001	4062966	DEC 13, 1994	NCE	FEB 18, 1993
18683 001	4393871	JUL 19, 2000		
/18689/001/	/3708579/	/JAN/02,/1992/		
18689 001	3708579	JAN 02, 1992		
18701 001	3438991	APR 15, 1986	NE	JAN 14, 1989
18703 001			I-42	MAY 30, 1989
18703 001			I-43	MAY 30, 1989
18703 002	4128658	DEC 05, 1995	NCE	JUN 09, 1993
	4521431	JUN 04, 2002	I-15	JUN 28, 1988
			I-42	MAY 30, 1989
			I-43	MAY 30, 1989
18705 001			NDF	OCT 31, 1988
18708 001	3845039	OCT 29, 1991	NCE	DEC 27, 1990
	3920818	NOV 18, 1992		
18713 001	/3839573/	/OCT/01,/1991/		
18731 001	3177634	FEB 20, 1990	NCE	SEP 29, 1991
	4182763	JAN 08, 1997		
18731 002	3177634	FEB 20, 1990	NCE	SEP 29, 1991
	4182763	JAN 08, 1997		
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/
18738 001	4055652	OCT 25, 1996	NCE	AUG 30, 1990
18754 002	3641127	FEB 08, 1989	NCE	JAN 09, 1991
18754 003	3641127	FEB 08, 1989	NCE	JAN 09, 1991
18768 001			I-46	SEP 04, 1989
/18770/001/	/4138581/	/FEB/06,/1996/	/NCE/	/DEC/28,/1989/
18770 001	4138581	FEB 06, 1998	NCE	DEC 28, 1989
18813 001	/3839573/	/OCT/01,/1991/		
18827 001	/3839573/	/OCT/01,/1991/		
18830 001	3900481	AUG 19, 1992	NCE	OCT 31, 1990
18830 001	4005209	JAN 25, 1994	NCE	OCT 31, 1990
18830 002	3900481	AUG 19, 1992	NCE	OCT 31, 1990
18830 002	4005209	JAN 25, 1994	NCE	OCT 31, 1990
18859 001	4211771	JUL 08, 1997	NCE	DEC 31, 1990
	RE29835	MAR 19, 1991		

(continued)

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
	18873 002	3954872	MAY 04, 1993	NCE	DEC 30, 1990
		4031244	JUN 21, 1994		
	18873 003	3954872	MAY 04, 1993	NCE	DEC 30, 1990
		4031244	JUN 21, 1994		
	18873 004	3954872	MAY 04, 1993	NCE	DEC 30, 1990
		4031244	JUN 21, 1994		
	18874 001	3697559	OCT 10, 1989	NDF	SEP 24, 1989
>_ADD_>	18874 001	4308264	DEC 29, 1998		
	18874 002	3697559	OCT 10, 1989	NDF	SEP 24, 1989
>_ADD_>	18874 002	4308264	DEC 29, 1998		
	18887 001	3686412	AUG 22, 1989	NDF	DEC 05, 1988
		3777033	AUG 22, 1989		
		3860618	JAN 14, 1992		
		4405598	SEP 20, 2000		
	18891 001	4559222	DEC 17, 2002		
	18891 002	4559222	DEC 17, 2002		
	18891 003	4559222	DEC 17, 2002		
	/18917/001/	/3857952/	/DEC/31,/1991/		
	18917 001	3857952	DEC 31, 1993		
	/18917/003/	/3857952/	/DEC/31,/1991/		
	18917 003	3857952	DEC 31, 1993		
	18928 001	4221778	SEP 09, 1997		
	18932 001			ODE	NOV 20, 1991
	18948 001			NCE	DEC 27, 1990
				ODE	DEC 27, 1992
	/18949/001/	/3878217/	/APR/15,/1992/	/NCE	/MAY/08,/1990/
	18949 001	3878217	APR 15, 1994	NCE	MAY 08, 1990
		/3886526/	/APR/23,/1991/		
		/3965257/	/JUN/22,/1993/		
		/3966940/	/JUN/29,/1993/		
		/4254129/	/MAR/03,/1998/		
		/4285957/	/AUG/25,/1998/		
	18956 001	4021481	MAY 03, 1994	NCE	DEC 26, 1990
		4250113	FEB 10, 19980		
	18956 002	4021481	MAY 03, 1994	NCE	DEC 26, 1990
		4250113	FEB 10, 1998		
	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		
		4616006	OCT 07, 2003		
	18985 002	4544554	JUL 23, 2002		
		4616006	OCT 07, 2003		
	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
	19028 001			NP	AUG 13, 1989
	19032 001	3632645	JAN 04, 1989	NCE	OCT 27, 1991
	/19044/001/	/4335095/	/JUN/15,/1999/	/NCE/	/DEC/23,/1990/
	19044 001	4335095	JUN 15, 1999	NCE	DEC 23, 1990
	19059 001	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
	19059 002	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
	19059 003	4138475	FEB 06, 1996	PETITION FOR EXCLUSIVITY PENDING	
	19069 001	/3839573/	/OCT/01,/1991/		
	19071 001			ODE	AUG 30, 1992
				NP	AUG 30, 1988
	19079 001			NE	FEB 11, 1989
	19081 002	4379454	APR 12, 2000	NDF	SEP 10, 1989
		4144317	SEP 09, 1992		
		3948262	JUL 29, 1992		
	19081 003	4379454	APR 12, 2000	NDF	SEP 10, 1989
		4144317	SEP 09, 1992		
		3948262	JUL 29, 1992		
	19084 001	4335125	JUN 15, 1999	NDF	DEC 31, 1988
	19090 001	4585790	APR 29, 2003		
	19107 001			NCE	OCT 17, 1990
	19107 001			ODE	OCT 17, 1992
	19193 001			NCE	OCT 31, 1991
	19194 001			NCE	NOV 11, 1990
				ODE	NOV 11, 1992
	19215 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990

(continued)

APPENDIX 6
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
19219 002	3641152	FEB 08, 1989	NCE	DEC 19, 1990
19221 001	4374829	FEB 22, 2000	NC	OCT 31, 1989
	4472380	SEP 18, 2001		
19257 001			NDF	APR 10, 1989
			ODE*	DEC 27, 1992
19259 001	3980778	SEP 14, 1993		
19260 001	3980778	SEP 14, 1993		
19264 001			ODE	OCT 16, 1991
19270 001	4252984	FEB 24, 1998	NCE	AUG 30, 1990
	4311708	JAN 19, 1999		
	4342783	AUG 03, 1999		
19322 001	3721687	MAR 20, 1990	NCE	DEC 27, 1990
19323 001	3721687	MAR 20, 1990	NCE	DEC 27, 1990
19359 001	4078071	MAR 07, 1995	NCE	NOV 25, 1990
19368 001	4205086	MAY 27, 1997	NCE	OCT 29, 1990
			ODE	OCT 29, 1992
19369 001	4215215	JUL 29, 1997	NCE	SEP 30, 1991
	4200647	APR 29, 1997		
19369 002	4215215	JUL 29, 1997	NCE	SEP 30, 1991
	4200647	APR 29, 1997		
19384 002	4146719	MAR 27, 1996	NCE	OCT 31, 1991
19412 001			NS	MAR 10, 1989
19412 002			NS	MAR 10, 1989
19412 003			NS	MAR 10, 1989
19412 004			NS	MAR 10, 1989
19415 001			NE	SEP 18, 1989
19425 001	4012444	MAR 15, 1994	NCE	AUG 01, 1994
	4066755	JAN 03, 1995		
19434 001	3950333	APR 13, 1993		
	4024271	MAY 17, 1994		
19435 001	4024163	MAY 17, 1994	NCE	MAR 31, 1991
19439 001			NS	JUN 13, 1989
19441 001			NC	JUL 11, 1989
19462 001	4283408	AUG 11, 1998	NCE	OCT 15, 1991
19462 002	4283408	AUG 11, 1998	NCE	OCT 15, 1991
> ADD > 19463 001	3655663	APR 11, 1989	NP	NOV 05, 1989
> ADD > 19463 001	4195085	MAR 25, 1997		
> ADD > 19463 002	3655663	APR 11, 1989	NP	NOV 05, 1989
> ADD > 19463 002	4195085	MAR 25, 1997		
19478 001	3644627	FEB 22, 1989		
	3784684	JAN 08, 1991		
19478 002	3644627	FEB 22, 1989		
	3784684	JAN 08, 1991		
> ADD > 19510 001	4283408	AUG 11, 1998	NCE	OCT 15, 1991
19518 001			NS	AUG 06, 1989
19600 001			NDF	OCT 30, 1989

*REFER TO APPENDIX I NARRATIVE

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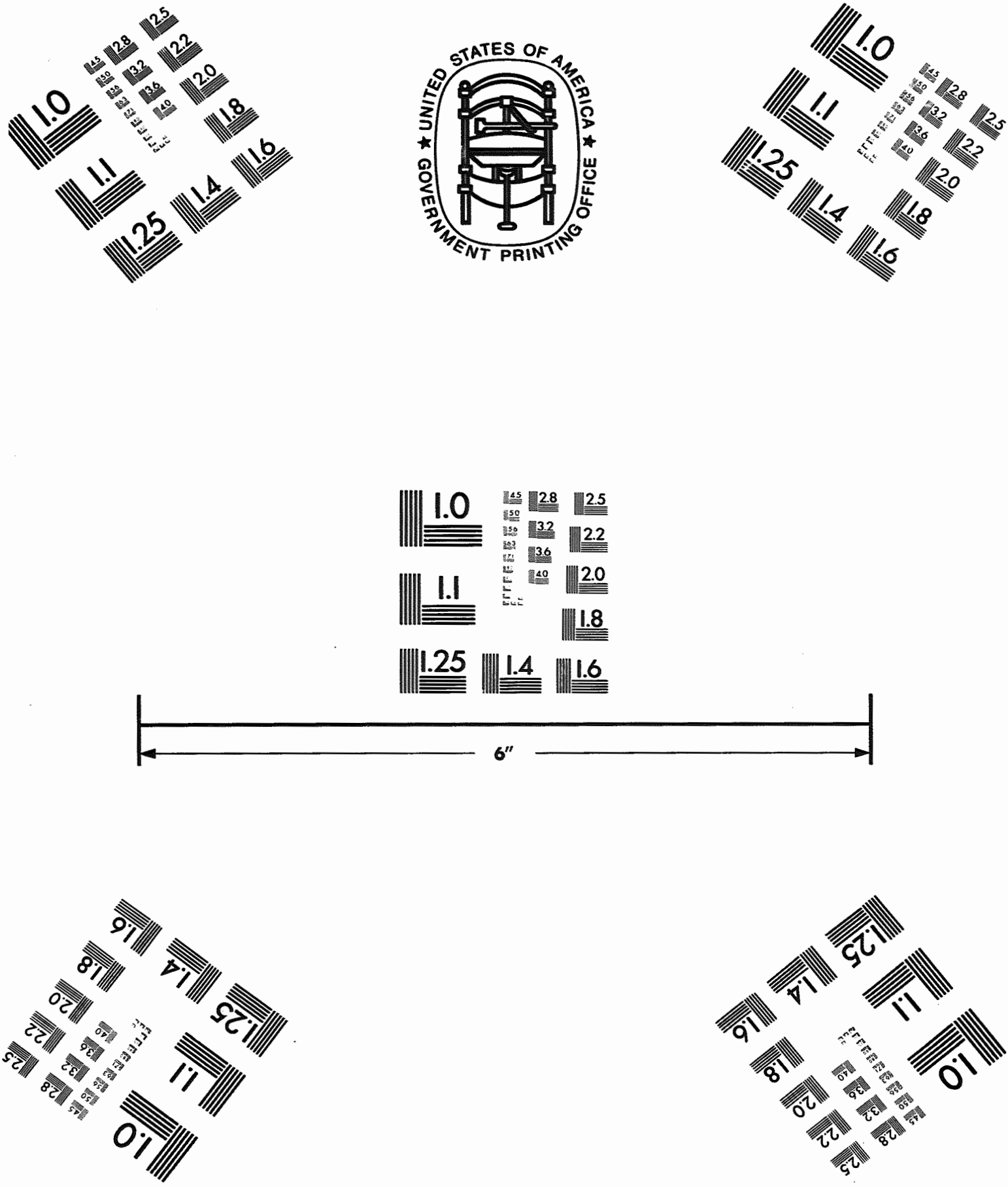
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