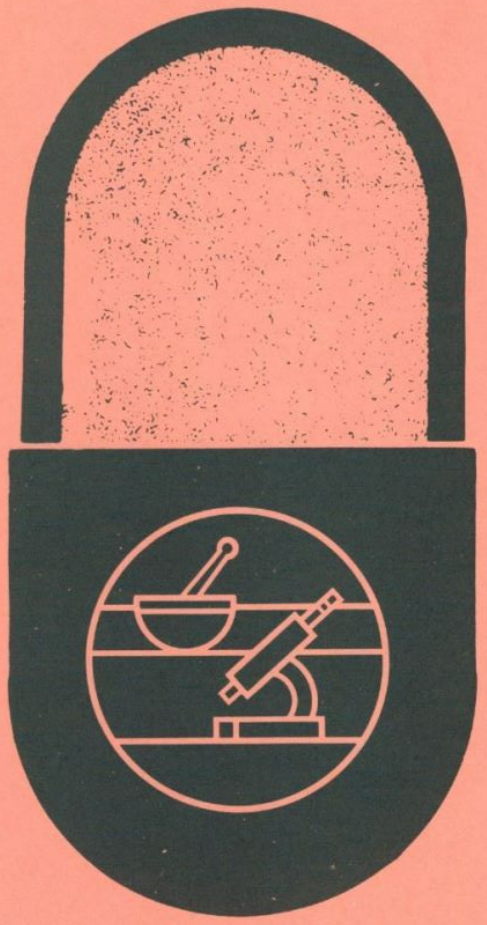
CUMULATIVE SUPPLEMENT 2
AUG'85-OCT'85



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

OCTOBER 1985

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*New Section

A. INTRODUCTION

*New Section

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CUMULATIVE SUPPLEMENT

OCTOBER 1985

A. INTRODUCTION

1. HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

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

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

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

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

Products discontinued from marketing will be flagged in this Cumulative Supplement with the " ə" 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

3. PREDNISONE BIOEQUIVALENCE

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

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

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

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

4. OTC DRUG PRODUCTS

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

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

5. PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

Products	Federal Register Reference
isosorbide dinitrate	AUG 3, 1984 (49 FR 31151)
nandrolone decanoate	JUL 15, 1983 (48 FR 32395)
neomycin sulfate with either: dexamethasone sodium phosphate, fluocinolone acetonide, flurandrenolide, hydrocortisone, or methylprednisolone acetate [topical anti-infectives for dermatologic use]	MAR 26, 1984 (49 FR 11888)
neomycin sulfate, polymyxin B sulfate, bacitracin zinc, and hydrocortisone [topical ointment]	MAY 4, 1984 (49 FR 19147)
nitroglycerin (capsule,controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
parenteral multivitamin products	SEP 17, 1984 (49 FR 36446)
phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
sulfanilamide and aminacrine	AUG 22, 1983 (48 FR 38097)
tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

6. 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)
DRUG PRODUCTS LISTED	8048
SINGLE SOURCE	2096 (26.0%)
MULTISOURCE(1)	5952 (74.0%)
THERAPEUTICALLY EQUIVALENT	4864 (60.5%)
NOT THERAPEUTICALLY EQUIVALENT	1054 (13.2%)
EXCEPTIONS(2)	25 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	-
NUMBER OF APPLICANTS	306

B. ACTIVITY FOR SUPPLEMENT NUMBER 2

	AUG '85	SEPT' 85	OCT '85	CUMULATIVE
DRUG PRODUCTS ADDED:	41	70	71	182
NEWLY APPROVED	40	70	69	179
DESI EFFECTIVE	1	0	0	1
REMARKETED	0	0	2	2
DRUG PRODUCTS REMOVED:	0	0	0	0
WITHDRAWN APPROVAL	0	0	0	0
RX TO OTC SWITCH	0	0	0	0
NET GAIN IN DRUG PRODUCTS	41	70	71	182
SINGLE SOURCE PRODUCTS APPROVED	7	8	6	21
MULTISOURCE DRUG PRODUCTS APPROVED	34	62	65	161
NEW MOLECULAR ENTITIES APPROVED:	2	0	3	5
AS THE ENTITY	0	0	2	2
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	2	0	1	3

(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-5 OF THE LIST)

B. DRUG PRODUCT LISTS

1. Prescription Drug Product List

2. OTC Drug Product List

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

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

TABLET; ORAL

> ADD >		SEDAPAP-10			
> ADD >	AB	MAYRAND	650MG;50MG*	N88944 001	
> ADD >				OCT 17, 1985	

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL

		ACETAMINOPHEN W/ CODEINE			
> DLT >/AA/		/VITARINE/	/300MG;30MG/	/N85917.001/	
		ACETAMINOPHEN W/ CODEINE #4			
> DLT >/AA/		/VITARINE/	/300MG;60MG/	/N87423.001/	
		ACETAMINOPHEN W/ CODEINE #2			
> DLT >/AA/		/VITARINE/	/300MG;15MG/	/N87433.001/	
> ADD >		ACETAMINOPHEN AND CODEINE			
> ADD >	AA	VITARINE	300MG;30MG	N85917 001	
> ADD >	AA		300MG;60MG	N87423 001	
> ADD >	AA		300MG;15MG	N87433 001	
> ADD >		ACETAMINOPHEN AND CODEINE PHOSPHATE #2			
> ADD >	AA	SUPERPHARM	300MG;15MG*	N89183 001	
> ADD >				OCT 18, 1985	
> ADD >		ACETAMINOPHEN AND CODEINE PHOSPHATE #3			
> ADD >	AA	SUPERPHARM	300MG;30MG*	N89184 001	
> ADD >				OCT 18, 1985	
> ADD >		ACETAMINOPHEN AND CODEINE PHOSPHATE #4			
> ADD >	AA	SUPERPHARM	300MG;60MG*	N89185 001	
> ADD >				OCT 18, 1985	

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL

		ACETAMINOPHEN AND HYDROCODONE BITARTRATE			
	AA	DM GRAHAM LABS	500MG;5MG*	N89006 001	
				AUG 09, 1985	
		BANCAP HC			
> DLT >/AA/		/ONEAL,JONES&FELDMAN//500MG;5MG/		/N87961.001/	
> DLT >				/MAR.17,.1983/	
> ADD >	AA	FOREST PHARM/FOREST	500MG;5MG	N87961 001	
> ADD >				MAR 17, 1983	

TABLET; ORAL

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

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL

		PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN			
	AB	ZENITH LABORATORIES	650MG;100MG*	N70146 001	
				AUG 02, 1985	

ACETAZOLAMIDE (PAGE 3-4)

TABLET; ORAL

		ACETAZOLAMIDE			
> ADD >	AB	DANBURY PHARMACAL	250MG*	N88882 001	
> ADD >				OCT 22, 1985	

ACETIC ACID, GLACIAL (PAGE 3-4)

SOLUTION/DROPS; OTIC

		BORCFAIR			
	AT	PHARMAFAIR	2%*	N88606 001	
				AUG 21, 1985	

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION

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

AMINOPHYLLINE (PAGE 3-10)

TABLET; ORAL

		AMINOPHYLLINE			
> DLT >	/BC/	/CORD LABORATORIES/	/100MG/	/N85262.002/	
> ADD >	AB	CORD LABORATORIES	100MG	N85262 002	

AMOXICILLIN (PAGE 3-15)

CAPSULE; ORAL

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

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)

CAPSULE; ORAL

> ADD >		LANORINAL			
> ADD >	AB	LANNETT	325MG;50MG;40MG*	N86996 003	
> ADD >				OCT 11, 1985	

ASPIRIN; CARISOPRODOL (PAGE 3-20)

TABLET; ORAL

> ADD >		CARISOPRODOL COMPOUND			
> ADD >	AB	BOLAR PHARMACEUTICAL	325MG;200MG¤	N88809 001	OCT 03, 1985
> ADD >					
		SOMA COMPOUND			
> ADD >	AB	WALLACE PHARMS/C-W	325MG;200MG	N12365 005	JUL 11, 1983

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

OINTMENT; TOPICAL

		CORTISPORIN			
AT		BURROUGHS WELLCOME	400 UNITS/GM;1%;EQ 3.5MG BASE/GM; 5,000 UNITS/GM	N50168 001	MAY 04, 1985
		NEOMYCIN & POLYMYXIN B SULFATES & BACITRACIN ZINC & HYDROCORTISONE			
AT		PHARMAFAIR	400 UNITS/GM;1%;EQ 3.5MG BASE/GM; 5,000 UNITS/GM¤	N62381 001	SEP 06, 1985

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

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC

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

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

INJECTABLE;INJECTION

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

CEFAMANDOLE NAFATE (PAGE 3-37)

INJECTABLE; INJECTION

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

CEFAZOLIN SODIUM (PAGE3-38)

INJECTABLE; INJECTION

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

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

CHLORAMPHENICOL (PAGE 3-42)

SOLUTION/DROPS; OPHTHALMIC

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

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL
CHLORTHALIDONE

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

> ADD > CIMETIDINE HYDROCHLORIDE; SODIUM CHLORIDE (PAGE 3-50)

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

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

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION
DEXTROSE 5% IN PLASTIC CONTAINER

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

DEXTROSE; SODIUM CHLORIDE (PAGE 3-70)

INJECTABLE; INJECTION
DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

> ADD > AP	ABBOTT LABORATORIES	5GM/100ML;225MG/100ML	N17606 001		
> ADD > AP	ABBOTT LABORATORIES	5GM/100ML;225MG/100ML¤	N19482 001	OCT 04, 1985	

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

> ADD > AP	ABBOTT LABORATORIES	5GM/100ML;300MG/100ML¤	N19486 001	OCT 04, 1985

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

> ADD > AP	ABBOTT LABORATORIES	5GM/100ML;450MG/100ML¤	N19484 001	OCT 04, 1985

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD > AP	ABBOTT LABORATORIES	5GM/100ML;900MG/100ML¤	N19483 001	OCT 04, 1985

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

DIAZEPAM (PAGE 3-72)

TABLET; ORAL
DIAZEPAM

AB	MYLAN PHARMS	2MG¤	N70323 001	SEP 04, 1985
AB		5MG¤	N70324 001	SEP 04, 1985
AB		10MG¤	N70325 001	SEP 04, 1985
AB	PARKE-DAVIS/W-L	2MG¤	N70209 001	SEP 04, 1985
AB		5MG¤	N70210 001	SEP 04, 1985
AB		10MG¤	N70222 001	SEP 04, 1985
AB	ZENITH LABORATORIES	2MG¤	N70360 001	SEP 04, 1985
AB		5MG¤	N70361 001	SEP 04, 1985
AB		10MG¤	N70362 001	SEP 04, 1985

VALIUM

AB	HOFFMANN-LA ROCHE	2MG	N13263 002
AB		5MG	N13263 004
AB		10MG	N13263 006

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

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION

DOPAMINE HCL

> ADD >	AP	ASTRA PHARM PRODS	40MG/ML*	N70087 001	OCT 23, 1985
> ADD >	AP		80MG/ML*	N70089 001	OCT 23, 1985
> ADD >	AP		80MG/ML*	N70090 001	OCT 23, 1985
> ADD >	AP		80MG/ML*	N70091 001	OCT 23, 1985
> ADD >	AP		160MG/ML*	N70092 001	OCT 23, 1985
> ADD >	AP		160MG/ML*	N70093 001	OCT 23, 1985
> ADD >	AP		160MG/ML*	N70094 001	OCT 23, 1985
> ADD >	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

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

DOXYCYCLINE HYCLATE (PAGE 3-79)

CAPSULE; ORAL

DORYX

> ADD >	AB	PARKE-DAVIS/W-L	EQ 100MG BASE*	N62653 001	OCT 30, 1985

TABLET; ORAL

DOXYCYCLINE HYCLATE

	AB	PARKE-DAVIS/W-L	EQ 100MG BASE*	N62593 001	AUG 28, 1985

DOXYLAMINE SUCCINATE (PAGE 3-80)

TABLET; ORAL

DOXYLAMINE SUCCINATE

> ADD >	AA	COPLEY PHARM	25MG*	N88900 001	OCT 08, 1985

EDROPHONIUM CHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION

ENLON

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

TENSILON

	AP	HOFFMANN-LA ROCHE	10MG/ML	N07959 001	

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-83)

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	

ERYTHROMYCIN (PAGE 3-83)

CAPSULE, ENTERIC-COATED PELLETS; ORAL

ERYC

		PARKE-DAVIS/W-L	250MG*	N62618 001	SEP 25, 1985

ERYC 125

> ADD >		PARKE-DAVIS/W-L	125MG*	N62643 001	OCT 24, 1985

> ADD > FLECAINIDE ACETATE (PAGE 3-92)

TABLET; ORAL

TAMBOCOR

> ADD >		RIKER LABS/3M	100MG*	N18830 001	OCT 31, 1985
> ADD >			200MG*	N18830 002	OCT 31, 1985

FLUOCINOLONE ACETONIDE (PAGE 3-92)

SOLUTION; TOPICAL

FLUOCINOLONE ACETONIDE

	AT	THAMES PHARMACAL	0.01%*	N89124 001	SEP 11, 1985

FLUOROMETHOLONE (PAGE 3-93)

OINTMENT; OPHTHALMIC

FML

		ALLERGAN PHARMS	0.1%*	N17760 001	SEP 04, 1985

FOLIC ACID (PAGE3-95)

TABLET; ORAL
FOLIC ACID

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

TABLET; ORAL
FUROSEMIDE

AB	BARR LABORATORIES	20MG*	N70043 001	SEP 26, 1985

GENTAMICIN SULFATE (PAGE 3-97)

INJECTABLE; INJECTION
GENTAFAIR

AP	PHARMAFAIR	EQ 40MG BASE/ML*	N62493 001	AUG 28, 1985

GLYCINE (PAGE 3-100)

SOLUTION; IRRIGATION
AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER

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

GLYCINE 1.5% IN PLASTIC CONTAINER

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

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

>ADD>	AP	LUITPOLD PHARMS	10 UNITS/ML*	N89063 001	OCT 09, 1985
>ADD>					
>ADD>	AP		100 UNITS/ML*	N89064 001	OCT 09, 1985

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

INJECTABLE; INJECTION
HYDRALAZINE HYDROCHLORIDE

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

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-108)

CAPSULE; ORAL
HYDRA-ZIDE

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

HYDROCHLOROTHIZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

AB	SUPERPHARM	25MG;25MG*	N89137 001	AUG 26, 1985

>DLT>	/HYDROCODONE; PHENYLTOLOXAMINE (PAGE 3-112)/				
>DLT>	/SUSPENSION; ORAL/				
>DLT>	/TUSSIONEX/				
>DLT>	/PENNWALT PHARM/	/EQ 5MG BASE/5ML;/			
>DLT>		/EQ 10MG BASE/5ML/	N16768 006/		

HYDROCORTISONE (PAGE 3-112)

OINTMENT; TOPICAL
HYDROCORTISONE IN ABSORBASE

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

HYDROCORTISONE BUTYRATE (PAGE 3-116)

CREAM; TOPICAL
LOCOID

>ADD>	BX	OWEN LABS/DERM PRODS	0.1%	N18795 001	JAN 07, 1983
>ADD>		HYDROCORTISONE BUTYRATE			
>ADD>	BX	∂ GIST-BROCADES	0.1%	N18514 001	MAY 31, 1982
>ADD>					

INDOMETHACIN (PAGE 3-122)

		CAPSULE; ORAL			
	AB	MYLAN PHARMS	50MG*	N70624 001	SEP 04, 1985
> ADD >	AB	WATSON LABS	25MG*	N70529 001	OCT 18, 1985
> ADD >					
> ADD >	AB		50MG*	N70530 001	OCT 18, 1985
> ADD >					
> ADD >		SUSPENSION; ORAL			
> ADD >		INDOCIN			
> ADD >		MS&D RES LABS/MERCK	25MG/5ML*	N18332 001	OCT 10, 1985
> ADD >					

LORAZEPAM (PAGE 3-132)

		TABLET; ORAL			
		ATIVAN			
	AB	WYETH LABS/AMHO	0.5MG	N17794 001	
	AB		1MG	N17794 002	
	AB		2MG	N17794 003	
		LORAZEPAM			
	AB	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			
> ADD >		∂ LEDERLE LABS/AM CYAN	EQ 10MG BASE	N17525 006	
> ADD >		∂	EQ 25MG BASE	N17525 007	
> ADD >		∂	EQ 50MG BASE	N17525 008	

MANNITOL (PAGE 3-134)

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

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

		TABLET; ORAL			
		MECLIZINE HCL			
	AA	SUPERPHARM	12.5MG*	N89113 001	AUG 20, 1985
	AA		25MG*	N89114 001	AUG 20, 1985

METHOTREXATE SODIUM (PAGE 3-143)

		INJECTABLE; INJECTION			
		FOLEX			
> ADD >	AP	ADRIA LABS/ERBAMONT	EQ 250MG BASE/VIAL*	N88954 001	OCT 24, 1985
> ADD >					
> ADD >		METHOTREXATE SODIUM			
> ADD >	AP	LYPHOMED	EQ 20MG BASE/VIAL*	N88935 001	OCT 11, 1985
> ADD >					
> ADD >	AP		EQ 50MG BASE/VIAL*	N88936 001	OCT 11, 1985
> ADD >					
> ADD >	AP		EQ 100MG BASE/VIAL*	N89937 001	OCT 11, 1985
> ADD >					
		MEXATE			
> ADD >	AP	BRISTOL LABS/B-M	EQ 250MG BASE/VIAL	N86358 004	

METHYLDOPA (PAGE 3-144)

		TABLET; ORAL			
		METHYLDOPA			
> ADD >	AB	LEDERLE LABS/AM CYAN	125MG*	N70070 003	OCT 15, 1985
> ADD >					
> ADD >	AB		250MG*	N70084 001	OCT 15, 1985
> ADD >					
> ADD >	AB		500MG*	N70085 001	OCT 15, 1985
> ADD >					

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

		TABLET; ORAL			
> ADD >		CLOPRA-"YELLOW"			
> ADD >	AB	QUANTUM PHARMICS	EQ 10MG BASE*	N70632 001	OCT 28, 1985
> ADD >					
		METOCLOPRAMIDE HCL			
> ADD >	AB	PUREPAC/KALIPHARMA	EQ 10MG BASE*	N70581 001	OCT 17, 1985
> ADD >					

METRONIDAZOLE (PAGE 3-148)

		TABLET; ORAL			
		METRONIDAZOLE			
> ADD >	AB	VITARINE	250MG	N18620 001	MAR 04, 1982
> ADD >					
> ADD >	AB		500MG	N18620 001	JUN 02, 1983
> ADD >					
		METRYL			
> DLT >	/AB/	/VITARINE/	/250MG/	/N18620 001/	/MAR 04, 1982/
> DLT >					
		METRYL 500			
> DLT >	/AB/	/VITARINE/	/500MG/	/N18620 002/	/JUN 02, 1983/
> DLT >					

HYDROCORTISONE BUTYRATE (PAGE 3-116)

OINTMENT; TOPICAL
LOCOID
>ADD > BX OWEN LABS/DERM PRODS 0.1% N19106 001
JUL 03, 1984
>ADD > HYDROCORTISONE BUTYRATE
>ADD > BX ◑ GIST-BROCADES 0.1% N18652 001
>ADD > OCT 29, 1982

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

SUSPENSION; OTIC
NEOMYCIN SULFATE, POLYMYXIN B SULFATE & HYDROCORTISONE
AT PHARMAFAIR 1%;EQ 3.5MG BASE/ML;
10,000 UNITS/ML¤ N62617 001
SEP 18, 1985

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

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

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

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

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
>ADD > HYDROXYZINE
>ADD > AP ELKINS-SINN/AHROBINS 50MG/ML N85551 002
HYDROXYZINE HCL
>DLT >/AP/ /ELKINS-SINN/AHROBINS/50MG/ML/ /N85551.002/

TABLET; ORAL
HYDROXYZINE HCL
>ADD > AB QUANTUM PHARMICS 10MG¤ N88540 001
>ADD > OCT 22, 1985
>ADD > AB 25MG¤ N88551 001
>ADD > OCT 22, 1985
>ADD > AB 50MG¤ N88529 001
>ADD > OCT 22, 1985

IBUPROFEN (PAGE 3-120)

TABLET; ORAL
IBUPROFEN
AB CHELSEA LABORATORIES 400MG¤ N70038 001
SEP 06, 1985
AB 600MG¤ N70041 001
SEP 06, 1985
AB DANBURY PHARMACAL 400MG¤ N70436 001
AUG 21, 1985
AB 600MG¤ N70437 001
AUG 21, 1985
AB MYLAN PHARMS 400MG¤ N70045 001
SEP 24, 1985
AB 600MG¤ N70057 001
SEP 24, 1985
AB ◑ PAR PHARMACEUTICALS 300MG¤ N70328 001
AUG 06, 1985
AB 400MG¤ N70329 001
AUG 06, 1985
AB 600MG¤ N70330 001
AUG 06, 1985
IBUPROHM
AB OHM LABORATORIES 400MG¤ N70469 001
AUG 29, 1985
MOTRIN
AB ◑ UPJOHN 300MG N17463 003
800MG¤ N17463 005
MAY 22, 1985

INDOMETHACIN (PAGE 3-122)

CAPSULE; ORAL
INDOMETHACIN
>ADD > AB DURAMED PHARMS 25MG¤ N70326 001
>ADD > OCT 18, 1985
>ADD > AB 50MG¤ N70327 001
>ADD > OCT 18, 1985

METRONIDAZOLE HYDROCHLORIDE (PAGE 3-148)

INJECTABLE; INJECTION

FLAGYL I.V.

> ADD > AP SEARLE PHARMS EQ 500MG BASE/VIAL N18353 001

> ADD >

METRONIDAZOLE HCL

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

> ADD >

> ADD > MONOOCTANOIN (PAGE 3-150)

> ADD > LIQUID; PERFUSION, BILIARY

> ADD > MOCTANIN

> ADD > ASCOT HOSP PHARMS 100% N19368 001 OCT 29, 1985

> ADD >

NALOXONE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

> ADD > NALOXONE

> ADD > AP ELKINS-SINN/AHROBINS 0.4MG/ML* N70298 001 SEP 24, 1986 : OCT 22, 1985

> ADD >

> ADD > AP 0.4MG/ML* N70299 001 SEP 24, 1986 : OCT 22, 1985

> ADD >

> ADD > AP 0.4MG/ML* N70496 001 SEP 24, 1986 : OCT 22, 1985

> ADD >

> ADD > AP WYETH LABS/AMHO 0.02MG/ML* N70188 001 SEP 24, 1986 : OCT 02, 1985

> ADD >

> ADD > AP 0.02MG/ML* N70189 001 SEP 24, 1986 : OCT 02, 1985

> ADD >

> ADD > AP 0.4MG/ML* N70190 001 SEP 24, 1986 : OCT 02, 1985

> ADD >

> ADD > AP 0.4MG/ML* N70191 001 SEP 24, 1986 : OCT 02, 1985

> ADD >

NARCAN

> ADD > AP DUPONT PHARMS/DUPONT 0.02MG/ML N16636 001

> ADD > AP 0.4MG/ML N16636 002

> DLT > /S/ 1MG/ML N16636 003 JUN 14, 1982

NITROGLYCERIN (PAGE 3-154)

> ADD > AEROSOL; ORAL

> ADD > NITROLINGUAL

> ADD > G POHL-BOSKAMP 0.4MG/SPRAY* N18705 001 OCT 31, 1985

> ADD >

INJECTABLE; INJECTION

NITROGLYCERIN

AP INTL MEDICATION SYS 5MG/ML* N70026 001 SEP 10, 1985

NYSTATIN (PAGE 3-156)

SUSPENSION; ORAL

NYSTATIN

> ADD > AA NASKA PHARMACAL 100,000 UNITS/ML* N62571 001 OCT 29, 1985

> ADD >

TABLET; VAGINAL

NYSTATIN

> ADD > AT SIDMAK LABORATORIES 100,000 UNITS* N62615 001 OCT 17, 1985

> ADD >

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

CREAM; TOPICAL

MYCO-TRIACET II

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

> ADD > MYTREX F

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

> ADD >

> ADD > NYSTATIN-TRIAMCINOLONE ACETONIDE

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

> ADD >

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

> ADD >

OINTMENT; TOPICAL

MYCOLOG-II

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

> ADD > MYTREX F

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

> ADD >

> ADD > NYSTATIN-TRIAMCINOLONE ACETONIDE

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

> ADD >

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

> ADD >

> ADD > NYSTATIN AND TRIAMCINOLONE ACETONIDE

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

> ADD >

PHENYTOIN SODIUM, EXTENDED (PAGE 3-169)

CAPSULE; ORAL

> DLT > /EXTENDED/PHENYTOIN SODIUM/

> DLT > /AB/ /BOLAR PHARMACEUTICAL/100MG/ /N88711 001/ /DEC 21, 1984/

> ADD > SETROL

> ADD > AB BOLAR PHARMACEUTICAL 100MG N88711 001 DEC 21, 1984

> ADD >

PHENYTOIN SODIUM, PROMPT (PAGE 3-169)

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

POTASSIUM CHLORIDE (PAGE 3-171)

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

POTASSIUM CITRATE (PAGE 3-173)

TABLET; ORAL
POTASSIUM CITRATE
UNIV TX HLTH SCI CTR 5MEQ* N19071 001 AUG 30, 1985

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

TABLET, CONTROLLED RELEASE; ORAL
PROCAINAMIDE HCL
ADD AB DANBURY PHARMACAL 250MG* N89026 001 OCT 22, 1985
ADD AB 500MG* N89027 001 OCT 22, 1985
ADD AB 750MG* N89042 001 OCT 22, 1985

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

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

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

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

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

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

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

CAPSULE; ORAL
SODIUM IODIDE I-123
ADD ③ BENEDICT NUCLR PHARM 400 UCI N18671 003 MAY 27, 1982

> ADD > SOMATREM (PAGE 3-195)

> ADD > INJECTABLE; INJECTION
> ADD > PROTROPIN
> ADD > GENENTECH 5MG/VIAL* N19107 001 OCT 17, 1985
> ADD >

SOMATROPIN (PAGE 3-195)

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

SULCONAZOLE NITRATE (PAGE 3-197)

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

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

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB SIDMAK LABORATORIES 400MG;80MG* N70215 001 JUN 02, 1987 : SEP 10, 1985
AB 800MG;160MG* N70216 001 JUN 02, 1987 : SEP 10, 1985
SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH
AB PLANTEX/IKAPHARM 800MG;160MG* N70037 001 JUN 02, 1987 : SEP 19, 1985
SULFAMETHOXAZOLE AND TRIMETHOPRIM SINGLE STRENGTH
AB PLANTEX/IKAPHARM 400MG;80MG* N70030 001 JUN 02, 1987 : SEP 19, 1985

SULFANILAMIDE (PAGE 3-199)

CREAM; VAGINAL
VAGITROL
LEMMON 15%* N88718 001 SEP 19, 1985

SULFINPYRAZONE (PAGE 3-200)

CAPSULE; ORAL
SULFINPYRAZONE
AB PAR PHARMACEUTICAL 200MG* N88934 001 SEP 06, 1985

TABLET; ORAL
SULFINPYRAZONE
AB PAR PHARMACEUTICAL 100MG* N88933 001 SEP 06, 1985

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

INJECTABLE; INJECTION
> DLT > /TECHNECOLL/
> DLT > /AP/ /MALLINCKRODT/ /N/A/ /N17059/001/

> ADD > SOLUTION; INJECTION, ORAL
> ADD > TECHNECOLL
> ADD > MALLINCKRODT N/A N17059 001

TEMAZEPAM (PAGE 3-203)

CAPSULE; ORAL
RESTORIL
> ADD > AB SANDOZ PHARMS/SANDOZ 15MG N18163 001
> ADD > AB 30MG N18163 002
> ADD > SOMAZ
> ADD > AB QUANTUM PHARMICS 15MG* N70564 001 OCT 15, 1985
> ADD > AB 30MG* N70547 001 OCT 15, 1985
> ADD >

THEOPHYLLINE (PAGE 3-206)

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

TABLET; ORAL
QUIBRON-T
MEAD JOHNSON/B-M 300MG* N88656 001 AUG 22, 1985

THEOPHYLLINE (PAGE 3-206)

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

TROPICAMIDE (PAGE 3-219)

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE
AT MAURRY BIOLOGICAL 1%* N88447 001
AUG 28, 1985

WARFARIN SODIUM (PAGE 3-221)

TABLET; ORAL
COUMADIN
/BX/ /DUPONT PHARMS/DUPONT/ 2.5MG/ /N09218 018/
AB DUPONT PHARMS/DUPONT 2.5MG N09218 018
WARFARIN SODIUM
AB COLMED LABORATORIES 2.5MG* N88720 001
AUG 06, 1985

DIPHENHYDRAMINE HCL (PAGE 3-225)

SYRUP; ORAL

> ADD > DIPHEN
> ADD > BAY LABORATORIES 12.5MG/5ML* N70118 001
> ADD > OCT 01, 1985

IBUPROFEN (PAGE 3-225)

TABLET; ORAL

> ADD > IBUPROFEN
> ADD > PAR PHARMACEUTICAL 200MG* N70481 001
> ADD > SEP 24, 1986 : OCT 18, 1985

INSULIN ZINC SUSPENSION BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION

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

PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-228)

CAPSULE, CONTROLLED RELEASE; ORAL

> DLT > /SUDAFED S.A./
> ADD > SUDAFED 12 HOUR

NO SEPTEMBER OR OCTOBER APPROVALS

C. APPENDICES

1. Orphan Drug Products with Exclusive Approval

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

3. Biopharmaceutic Guidance Availability List

4. ANDA Suitability Petitions Approved and Denied List

5. Exclusivity Terms

6. Prescription and OTC Drug Product Patent and Exclusivity Data

APPENDIX 1

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

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

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

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

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

Biologicals, Antibiotics or Drugs that have been approved under Section 505 of the Act for marketing and have been given orphan drug exclusive approval will be noted by the abbreviation ODE in the Patent and Exclusivity Data Appendix.

BIOLOGICAL PRODUCTS

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

APPENDIX I

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
Pentamidine Isethionate 300mg/ml	Pentam 300 Injectable; Injection	LyphoMed	19264 001 Oct 16, 1984	ODE Oct 16, 1991
Naltrexone Hydrochloride 50mg	Trexan Tablet; Oral	Dupont Pharms	18932 001 Nov 20, 1984	ODE Nov 20, 1991
Potassium Citrate 5meq	Urocit-K Tablet; Oral	Univ of Tx Hlth Sci Ctr	19071 001 Aug 30, 1985	ODE Aug 30, 1992
Monooctanoin 100%	Moctanin Liquid; Perfusion Biliary	Ascot Hosp Pharms	19-368 001 Oct 29, 1985	ODE Oct 29, 1992

APPENDIX 2

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

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

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

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

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

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

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

Aminophylline
Tablet; Oral
100mg
200mg

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

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

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

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

Aspirin; Carisoprodol
Tablet; Oral
325mg; 200mg

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

Aspirin; Meprobamate
Tablet; Oral
325mg; 200mg

Aspirin; Methocarbamol
Tablet; Oral
325mg; 200mg

Chlorothiazide
Tablet; Oral
250mg

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

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

APPENDIX 3

BIOPHARMACEUTIC GUIDANCE AVAILABILITY LIST

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

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

*New Addition

(continued)

APPENDIX 3

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

*New Addition

APPENDIX 4

ANDA SUITABILITY PETITIONS

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

I. Petitions Approved

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Acetaminophen; Hydrocodone Bitartrate Solution; Oral	500mg/15ml 5mg/15ml	84 P-0391/CP	New Dosage Form	Approved Jul 2, 1985
Acetaminophen; Oxycodone Hydrochloride Solution; Oral	325mg/5ml 5mg/5ml	85 P-0085/CP	New Dosage Form	Approved Aug 23, 1985
Acetaminophen Suppository; Rectal	80mg	85 P-0403/CP	New Dosage Form (Pediatric)	Approved Oct 16, 1985
Benztropine Mesylate Syrup; Oral	0.5mg/5ml	85 P-0423/CP	New Dosage Form	Approved Oct 16, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Chlorhexidine Gluconate Solution; Topical	1.5%	84 P-0417/CP	New Strength	Approved Sep 18, 1985
Diazepam Solution; Oral	5mg/5ml	85 P-0090/CP	New Dosage Form	Approved Sep 19, 1985
Diphenhydramine Hydrochloride Concentrate; Oral	50mg/ml	84 P-0174/CP	New Strength	Approved Sep 11, 1985
Disulfiram Suspension; Oral	500mg/30ml	85 P-0215/CP	New Dosage Form	Approved Oct 8, 1985
Fluorouracil Injectable; Injection	25mg/ml	85 P-0208/CP	New Strength	Approved Oct 8, 1985
Flurazepam Concentrate; Oral	30mg/ml	85 P-0081/CP	New Dosage Form	Approved Jul 10, 1985
Flurazepam Hydrochloride Solution; Oral	15mg/5ml	85 P-0091/CP	New Dosage Form	Approved Oct 25, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Furosemide Solution; Oral	40mg/5ml	85 P-0106/ CP0002	New Strength	Approved Sep 19, 1985
Furosemide Concentrate; Oral	80mg/ml	85 P-0106/CP	New Strength	Approved Sep 19, 1985
Haloperidol Solution; Oral	5mg/5ml	85 P-0080/CP	New Strength	Approved Sep 19, 1985
Hydralazine Hydrochloride Solution; Oral	25mg/5ml	85 P-0074/CP	New Dosage Form	Approved Jul 3, 1985
Ibuprofen Capsule; Oral	200mg	84 P-0383/CP	New Dosage Form	Approved Jun 25, 1985
Indomethacin Suspension; Oral	25mg/5ml	85 P-0077/ CP0002	New Dosage Form	Approved Jul 19, 1985
Ketoconazole Suspension; Oral	20mg/ml	85 P-0147/CP	New Dosage Form	Approved Sep 27, 1985
Meperidine Hydrochloride Concentrate; Oral	100mg/ml	84 P-0175/CP	New Strength	Approved Jun 7, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Methyldopate Hydrochloride Injectable; Injection	50mg/ml 10ml/vial	85 P-0404/CP	New Strength	Approved Oct 25, 1985
Methyltestosterone Capsule; Oral	25mg	85 P-0067/CP	New Dosage Form	Approved Aug 23, 1985
Nitroglycerin Injectable; Injection	10mg/ml	85 P-0134/CP	New Strength	Approved Sep 19, 1985
Probucol Tablet; Oral	500mg	85 P-0337/CP	New Strength	Approved Oct 25, 1985
Procainamide Hydrochloride Tablet; Oral	375mg	85 P-0125/CP	New Strength	Approved Sep 19, 1985
Propranolol Hydrochloride Solution; Oral	40mg/5ml	85 P-0073/CP	New Dosage Form	Approved Jul 8, 1985
Propranolol Hydrochloride Concentrate; Oral	80mg/ml	85 P-0073/ CP0002	New Dosage Form	Approved Jul 19, 1985
Propranolol Hydrochloride Solution; Oral	20mg/5ml	85 P-0073/ CP0003	New Dosage Form	Approved Sep 24, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Propranolol Hydrochloride Tablet, Constant-Release; Oral	160mg	85 P-0129/CP	New Dosage Form	Approved Sep 25, 1985
Propranolol Hydrochloride Tablet, Controlled Release; Oral	80mg 120mg 160mg	85 P-0197/CP	New Dosage Form	Approved Sep 27, 1985
Scopolamine Transdermal System/24 Hour Film, Controlled Release; Percutaneous	1mg	85 P-0168/CP	New Strength (Dosing Interval)	Approved Sep 27, 1985
Theophylline Capsule; Oral	150mg 300mg	85 P-0175/CP	New Strength	Approved Oct 8, 1985
Vincristine Sulfate Injectable; Injection	2mg/vial	85 P-0016/CP	New Dosage Form	Approved Nov 8, 1985

APPENDIX 4

II. Petitions Denied

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	650mg 10mg	85 P-0015/CP	New Strength	Denied Nov 7, 1985
Acetaminophen; Hydrocodone Bitartrate Tablet; Oral	750mg 7.5mg	85 P-0169/CP	New Strength	Denied Nov 7, 1985
Aminocaproic Acid Injectable; Injection	500mg/ml	85 P-0064/CP	New Strength	Denied May 29, 1985
Aminophylline Injectable; Injection	10mg/ml	85 P-0066/CP	New Strength	Denied May 3, 1985
Aminophylline Injectable; Injection	50mg/ml	85 P-0066/CP	New Strength	Denied May 3, 1985
Aspirin; Chlorzoxazone Tablet; Oral	325mg 250mg	85 P-0071/CP	New Combination	Denied Sep 3, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 7.5mg	85 P-0101/CP	New Combination	Denied Sep 11, 1985
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 15mg	85 P-0101/CP	New Combination	Denied Sep 11, 1985
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 30mg	85 P-0101/CP	New Combination	Denied Sep 11, 1985
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 60mg	85 P-0101/ CP0002	New Combination	Denied Sep 11, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Codeine Phosphate; Ibuprofen Capsule; Oral	30mg 200mg	84 P-0388/CP	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Capsule; Oral	60mg 200mg	84 P-0388/CP	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Tablet; Oral	30mg 200mg	84 P-0388/CP	New Combination	Denied Sep 16, 1985
Codeine Phosphate; Ibuprofen Tablet; Oral	60mg 200mg	84 P-0388/CP	New Combination	Denied Sep 16, 1985
Diatrizoate Meglumine; Lidocaine Hydrochloride Injectable; Injection	60% 1.5mg/ml	84 P-0325/CP	New Combination	Denied Sep 3, 1985
Diazepam Intensol Concentrate; Oral	10mg/ml	85 P-0075/CP	New Dosage Form	Denied Sep 24, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Tri-Phasic Contraceptive Tablet; Oral(21 and 28 days) Ethinyl Estradiol Norethindrone Ethinyl Estradiol Norethindrone Ethinyl Estradiol Norethindrone	 0.05mg 0.5mg 0.05mg 0.75mg 0.05mg 1.0mg	84 P-0443/CP	New Strength (Dose Schedule)	Denied Sep 3, 1985
Fluphenazine Hydrochloride Injectable; Injection	5mg/ml	85 P-0019/CP	New Strength	Denied Oct 25, 1985
Heparin Sodium Injectable; Injection	2000 Units/ml	85 P-0065/CP	New Strength	Denied May 29, 1985
Heparin Sodium Injectable; Injection	4000 Units/ml	85 P-0065/CP	New Strength	Denied May 29, 1985
Ibuprofen; Oxycodone Hydrochloride Capsule; Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Ibuprofen; Oxycodone Hydrochloride Tablet; Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985
Indomethacin Tablet, Constant Release; Oral	75mg	85 P-0026/CP	New Dosage Form	Denied Sep 16, 1985
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0062/CP	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0062/ CP0002	New Strength	Denied May 29, 1985
Metronidazole Sponge; Vaginal	50-125mg/ Sponge	85 P-0117/CP	New Dosage Form	Denied Oct 8, 1985
Nitroglycerin Transdermal System	None Given	84 P-0302/CP	New Dosage Form (New Matrix)	Denied Jul 29, 1985
Triamcinolone Acetonide Suspension; Injection	2.5mg/ml	85 P-0001/CP	New Strength	Denied Mar 4, 1985
Triamcinolone Acetonide Suspension; Injection	3mg/ml	84 P-0240/CP	New Strength	Denied Mar 4, 1985

APPENDIX 5

EXCLUSIVITY TERMS

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

ABBREVIATIONS

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

REFERENCES

NEW DOSING SCHEDULE

D-1	ONCE A DAY APPLICATION
D-2	ONCE DAILY DOSING
D-3	SEVEN DAYS/SEVEN DAYS/SEVEN DAYS DOSING SCHEDULE
D-4	SEVEN DAYS/FOURTEEN DAYS DOSING SCHEDULE
D-5	TEN DAYS/ELEVEN DAYS DOSING SCHEDULE
D-6	SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE
D-7	BID DOSING
D-8	INTRAVENOUS, EPIDURAL AND INTRATHECAL DOSING
D-9	NARCOTIC OVERDOSE IN ADULTS
D-10	NARCOTIC OVERDOSE IN CHILDREN
D-11	POSTOPERATIVE NARCOTIC DEPRESSION IN CHILDREN

(continued)

APPENDIX 5

(continued)

NEW INDICATION

I-1	SEVERE HYPERTENSION IN PEDIATRICS AND NON-MALIGNANT HYPERTENSION
I-2	DYSMENORRHEA
I-3	TREATMENT OF TINEA VERSICOLOR
I-4	SYMPTOMATIC GASTROESOPHAGEAL REFLUX
I-5	NEPHROTOMOGRAPHY
I-6	CONTRAST ENHANCEMENT IN CRANIAL COMPUTED TOMOGRAPHY
I-7	VENOGRAPHY OF LOWER EXTREMITIES
I-8	WHOLE-BODY COMPUTED TOMOGRAPHY
I-9	GATED CARDIAC POOL IMAGING
I-10	POST-MYOCARDIAL INFARCTION
I-11	COLORECTAL SURGERY
I-12	NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY
I-13	CISPLATIN INDUCED EMESIS
I-14	DIABETIC GASTROPARESIS
I-15	SHORT TERM TREATMENT OF GASTRIC ULCER DISEASE
I-16	ACROMEGALY
I-17	PITUITARY TUMORS
I-18	POSTMENOPAUSAL OSTEOPOROSIS
I-19	ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
I-20	CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE
I-21	ACUTE/OTITIS/MEDIA
I-22	EXERCISE INDUCED BRONCHOSPASMS
I-23	MYOCARDIAL INFARCTION OR STROKE
I-24	COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL
I-25	BLASTOMYCOSES DERMATITIDES
I-26	PEDIATRIC SUBARACHNOID VASCULAR
I-27	PETRIELLIDIUM BOYDII INFECTION
I-28	HEREDITARY ANGIOEDEMA

(continued)

APPENDIX 5

(continued)

NEW INDICATION

	I-29	INTRACORONARY USE
	I-30	PEDIATRIC USE
	I-31	DIRECT ISOTOPIC CYSTOGRAPHY
	I-32	POSTPARTUM HEMORRHAGE
	I-33	USE IN METHODONE INDUCED RESPIRATORY DEPRESSION
	I-34	PROLACTIN SECRETING ADENOMAS
	I-35	ANGINA PECTORIS DUE TO CORONARY ATHEROSCLEROSIS
	I-36	ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
>ADD>	I-37	SPINAL ANESTHESIA

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 OR OCTOBER ACTIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
12365 005	4534973	AUG 13, 2002		
12366 002	4534974	AUG 13, 2002		
/16273 001/	/4324779/	/APR 13, 1999/		
/16273 002/	/4324779/	/APR 13, 1999/		
/16273 003/	/4324779/	/APR 13, 1999/		
/16363 001/	/4324779/	/APR 13, 1999/		
16636 002			D-9	SEP 24, 1986
			D-10	
			D-11	
			I-33	
16983 001			I-36	SEP 09, 1988

	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	3993966	DEC 21, 1993	/NS/	/SEP 24, 1986/
>_DLT_>	17613 001	/3839573/	/OCT 01, 1991/		
>_DLT_>	17619 001	/3839573/	/OCT 01, 1991/		
	/17688 001/	/4324779/	/APR 13, 1999/		
	17760 001			NDF	SEP 04, 1988
	17768 001	3855140	DEC 17, 1991		
		3960745	DEC 17, 1991		
>_DLT_>	17717 001	/3839573/	/OCT 01, 1991/		

(continued)

APPENDIX 6

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

(continued)

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
>ADD<	17862 001	4536386	AUG 20, 2002		
	17970 001	4536516	AUG 20, 2002		
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		/4100347/	/JUL/11,/1995/		
		/3927002/	/DEC/16,/1992/		
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		/4100347/	/JUL/11,/1995/		
		/3927002/	/DEC/16,/1992/		
	/18154 001/	/3461461/	/AUG 12,/1986/		
	18154 001	3461461	MAY 07, 1985		
	/18154 003/	/3461461/	/AUG 12,/1986/		
	18154 003	3461461	MAY 07, 1985		
>DLT<	18181 001	/3839573/	/OCT/01,/1991/		
>DLT<	18182 001	/3839573/	/OCT/01,/1991/		
>DLT<	18183 001	/3839573/	/OCT/01,/1991/		
>DLT<	18230 001	/3839573/	/OCT/01,/1991/		
	18240 001			I-35	SEP 04, 1988
	18240 002			I-35	SEP 04, 1988
>ADD<	18401 001	3433791	MAR 18, 1986		
	18423 001	3855140	DEC 17, 1991		
		3960745	DEC 17, 1991		
	18482 001	3784684	JAN 08, 1991		
	18509 001			NP	AUG 07, 1988
	18513 002			ODE	JUL 28, 1990
>ADD<	18683 001	4393871	JUL 19, 2000		
>ADD<	18705 001			NDF	OCT 31, 1988
>DLT<	18713 001	/3839573/	/OCT/01,/1991/		
	18738 001	4055652	OCT 25, 1994	NCE	AUG 30, 1990
>DLT<	18813 001	/3839573/	/OCT/01,/1991/		
>DLT<	18827 001	/3839573/	/OCT/01,/1991/		
>ADD<	18830 001	3900481	AUG 19, 1992	NCE	OCT 31, 1990
>ADD<	18830 001	4005209	JAN 25, 1994	NCE	OCT 31, 1990
>ADD<	18830 002	3900481	AUG 19, 1992	NCE	OCT 31, 1990
>ADD<	18830 002	4005209	JAN 25, 1994	NCE	OCT 31, 1990
>ADD<	18932 001			ODE	NOV 20, 1991
>ADD<	18985 001	4544554	JUL 23, 2002		
>ADD<	18985 002	4544554	JUL 23, 2002		
	18928 001	4221778	SEP 09, 1997		
	19071 001			ODE	AUG 30, 1992
				NP	AUG 30, 1988
	19011 001			NP	SEP 24, 1986
>DLT<	19069 001	/3839573/	/OCT/01,/1991/		
>ADD<	19107 001			NCE	OCT 17, 1990
	19259 001	3980778	SEP 14, 1993		
	19260 001	3980778	SEP 14, 1993		
	19264 001			ODE	OCT 16, 1991
	19270 001	4252984	FEB 24, 1998	NCE	AUG 30, 1990
		4311708	JAN 19, 1999		
		4342783	AUG 03, 1999		
>ADD<	19368 001	4205086	MAY 27, 1997	NCE	OCT 29, 1990
				ODE	OCT 29, 1992

SUBSCRIPTION FORM

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

MAIL TO:

DATE:

Superintendent of Documents
Government Printing Office
Washington, DC 20402
(202) 783-3238

PURCHASER:

SHIP TO:
(If different than purchaser)

CONTACT:

TELEPHONE (Include Area Code)

METHOD OF PAYMENT

[ ] Charge my GPO Account No. _____
[ ] Purchase Order Number _____
[ ] Check enclosed for $_____
(Make check payable to Superintendent of Documents)

AUTHORIZING SIGNATURE

DATE:

DESCRIPTION	QUANTITY	UNIT PRICE	TOTAL PRICE
The 6th Edition will be published in October 1985. Subscription includes the Approved Drug Products List and monthly Cumulative Supplements.			
DOMESTIC		@ $103.00	$
FOREIGN		@ $128.75	$
ENTER TOTAL			$