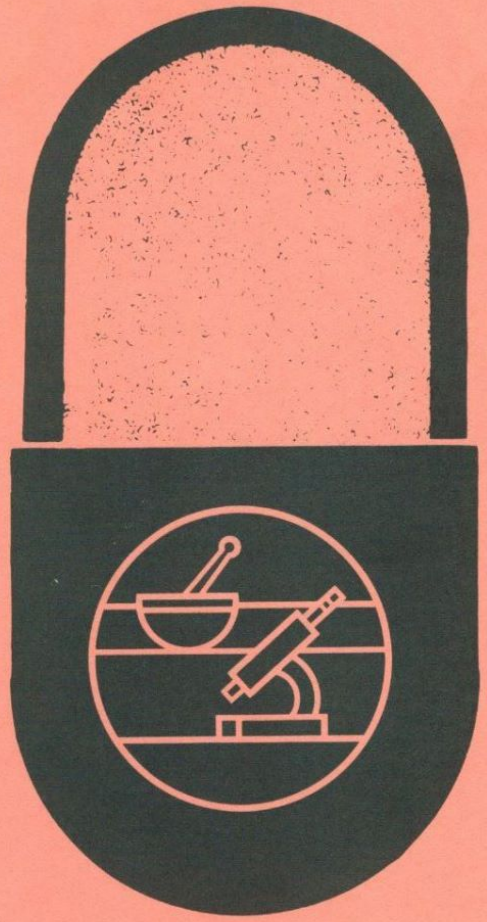
CUMULATIVE SUPPLEMENT 1
AUG'85-SEP'85



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

SEPTEMBER 1985

CONTENTS

A. INTRODUCTION

1. How to Use the Cumulative Supplement
2. Applicant Name Changes
3. Products Requiring Revised Labeling for Full Approval
4. Report of Counts for the Prescription Drug Product List

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A. INTRODUCTION

1. HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

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

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

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

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

3. 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)

4. 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 PRESCRIPTION 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 1

	AUG '85	SEPT '85	CUMULATIVE
DRUG PRODUCTS ADDED:	41	70	111
NEWLY APPROVED	40	70	110
DESI EFFECTIVE	1	0	1
REMARKETED	0	0	0
DRUG PRODUCTS REMOVED:	0	0	0
WITHDRAWN APPROVAL	0	0	0
RX TO OTC SWITCH	0	0	0
NET GAIN IN DRUG PRODUCTS	41	70	111
SINGLE SOURCE PRODUCTS APPROVED	7	8	15
MULTISOURCE DRUG PRODUCTS APPROVED	34	62	96
NEW MOLECULAR ENTITIES APPROVED:	2	0	2
AS THE ENTITY	0	0	0
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	2	0	2

(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; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL
ACETAMINOPHEN AND HYDROCODONE BITARTRATE

> ADD >	AA	DM GRAHAM LABS	500MG;5MG¤	N89006 001	
> ADD >				AUG 09, 1985	

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

> ADD >	AB	ZENITH LABORATORIES	650MG;100MG¤	N70146 001	
> ADD >				AUG 02, 1985	

ACETIC ACID, GLACIAL (PAGE 3-4)

SOLUTION/DROPS; OTIC
BOROFAIR

> ADD >	AT	PHARMAFAIR	2%¤	N88606 001	
> ADD >				AUG 21, 1985	

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION
AMINOSYN-PF 7%

> ADD >		ABBOTT LABORATORIES	7%¤	N19398 001	
> ADD >				SEP 06, 1985	

AMOXICILLIN (PAGE 3-15)

CAPSULE; ORAL
AMOXICILLIN

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

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

OINTMENT; TOPICAL
CORTISPORIN

> ADD >	AT	BURROUGHS WELLCOME	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;		
> ADD >			5,000 UNITS/GM	N50168 001	
> ADD >				MAY 04, 1985	

NEOMYCIN & POLYMYXIN B SULFATES & BACITRACIN ZINC & HYDROCORTISONE

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

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

LOTION; TOPICAL
ALPHATREX

> ADD >	AB	SAVAGE LABS/ALTANA	EQ 0.05% BASE¤	N70273 001	
> ADD >				AUG 12, 1985	

BETAMETHASONE DIPROPIONATE

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

> ADD > BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

> ADD > SOLUTION/DROPS; OPHTHALMIC
> ADD > BETOPTIC

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

CEFAMANDOLE NAFATE (PAGE 3-37)

INJECTABLE; INJECTION
MANDOL

> ADD >			EQ 1GM BASE/VIAL¤	N62560 001	
> ADD >				SEP 10, 1985	
> ADD >			EQ 2GM BASE/VIAL¤	N62560 002	
> ADD >				SEP 10, 1985	

CEFAZOLIN SODIUM (PAGE3-38)

INJECTABLE; INJECTION
KEFZOL

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

CEPHALOTHIN SODIUM (PAGE 3-40)

INJECTABLE; INJECTION
CEPHALOTHIN SODIUM

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

CEPHALOTHIN SODIUM (PAGE 3-40)

INJECTABLE; INJECTION
KEFLIN

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

CHLORAMPHENICOL (PAGE 3-42)

SOLUTION/DROPS; OPHTHALMIC
CHLORAMPHENICOL

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

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL
CHLORTHALIDONE

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

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION
DEXTROSE 5% IN PLASTIC CONTAINER

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

DIAZEPAM (PAGE 3-72)

TABLET; ORAL
DIAZEPAM

> ADD >					
> ADD >	AB	LEDERLE LABS/AM CYAN	2MG¤	N70226 001	SEP 26, 1985
> ADD >					
> ADD >	AB		5MG¤	N70227 001	SEP 26, 1985
> ADD >					
> ADD >	AB		10MG¤	N70228 001	SEP 26, 1985
> ADD >					
> ADD >	AB	MYLAN PHARMS	2MG¤	N70323 001	SEP 04, 1985
> ADD >					
> ADD >	AB		5MG¤	N70324 001	SEP 04, 1985
> ADD >					
> ADD >	AB		10MG¤	N70325 001	SEP 04, 1985
> ADD >					

DIAZEPAM (PAGE 3-72)

TABLET; ORAL
DIAZEPAM

> ADD >					
> ADD >	AB	PARKE-DAVIS/W-L	2MG¤	N70209 001	SEP 04, 1985
> ADD >					
> ADD >	AB		5MG¤	N70210 001	SEP 04, 1985
> ADD >					
> ADD >	AB		10MG¤	N70222 001	SEP 04, 1985
> ADD >					
> ADD >	AB	ZENITH LABORATORIES	2MG¤	N70360 001	SEP 04, 1985
> ADD >					
> ADD >	AB		5MG¤	N70361 001	SEP 04, 1985
> ADD >					
> ADD >	AB		10MG¤	N70362 001	SEP 04, 1985
> ADD >					

VALIUM

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

DIFLORASONE DIACETATE (PAGE 3-74)

CREAM; TOPICAL
DIFLORASONE DIACETATE

> ADD >					
> ADD >	BX	UPJOHN	0.05%¤	N19259 001	AUG 28, 1985
> ADD >					

FLORONE

> ADD >	BX	UPJOHN	0.05%	N17741 001

OINTMENT; TOPICAL
DIFLORASONE DIACETATE

> ADD >					
> ADD >	BX	UPJOHN	0.05%¤	N19260 001	AUG 28, 1985
> ADD >					

FLORONE

> ADD >	BX	UPJOHN	0.05%	N17994 001

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION
DOPAMINE HCL

> ADD >	AP	SOLOPAK LABORATORIES	40MG/ML¤	N70011 001	AUG 29, 1985
> ADD >					
> ADD >	AP		40MG/ML¤	N70046 001	AUG 29, 1985
> ADD >					
> ADD >	AP		80MG/ML¤	N70047 001	AUG 29, 1985
> ADD >					

DOPASTAT

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

DOXYCYCLINE HYCLATE (PAGE 3-79)

TABLET; ORAL
DOXYCYCLINE HYCLATE

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

EDROPHONIUM CHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION
ENLON

> ADD >					
> ADD >	AP	ANAQUEST/BOC	10MG/ML¤	N88873 001	
> ADD >				AUG 06, 1985	

TENSILON

> ADD >	AP	HOFFMANN-LA ROCHE	10MG/ML	N07959 001	

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION
LIDOCAINE HCL AND EPINEPHRINE

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

XYLOCAINE W/ EPINEPHRINE

> ADD >	AP	ASTRA PHARM PRODS	0.005MG/ML;1.5%	N10418 010	

ERYTHROMYCIN (PAGE 3-83)

CAPSULE, ENTERIC-COATED PELLETS; ORAL
ERYC

> ADD >		PARKE-DAVIS/W-L	250MG¤	N62618 001	
> ADD >				SEP 25, 1985	

FLUOCINOLONE ACETONIDE (PAGE 3-92)

SOLUTION; TOPICAL
FLUOCINOLONE ACETONIDE

> ADD >	AT	THAMES PHARMACAL	0.01%¤	N89124 001	
> ADD >				SEP 11, 1985	

FLUOROMETHOLONE (PAGE 3-93)

OINTMENT; OPHTHALMIC
FML

> ADD >					
> ADD >		ALLERGAN PHARMS	0.1%¤	N17760 001	
> ADD >				SEP 04, 1985	

FOLIC ACID (PAGE3-95)

TABLET; ORAL
FOLIC ACID

> ADD >	AA	PIONEER PHARMS	1MG¤	N88949 001	
> ADD >				SEP 13, 1985	

FUROSEMIDE (PAGE 3-96)

INJECTABLE; INJECTION
FUROSENIDE

> ADD >	AP	ASTRA PHARM PRODS	10MG/ML¤	N70014 001	
> ADD >				SEP 09, 1985	
> ADD >	AP		10MG/ML¤	N70095 001	
> ADD >				SEP 09, 1985	
> ADD >	AP		10MG/ML¤	N70096 001	
> ADD >				SEP 09, 1985	

TABLET; ORAL
FUROSEMIDE

> ADD >	AB	BARR LABORATORIES	20MG¤	N70043 001	
> ADD >				SEP 26, 1985	

GENTAMICIN SULFATE (PAGE 3-97)

INJECTABLE; INJECTION
GENTAFAIR

> ADD >					
> ADD >	AP	PHARMAFAIR	EQ 40MG BASE/ML¤	N62493 001	
> ADD >				AUG 28, 1985	

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

INJECTABLE; INJECTION
HYDRALAZINE HYDROCHLORIDE

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

HYDROCHLOROTHIZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

> ADD >					
> ADD >	AB	SUPERPHARM	25MG;25MG¤	N89137 001	
> ADD >				AUG 26, 1985	

HYDROCORTISONE (PAGE 3-112)

OINTMENT; TOPICAL
HYDROCORTISONE IN ABSORBASE

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

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

SUSPENSION; OTIC

NEOMYCIN SULFATE, POLYMYXIN B SULFATE & HYDROCORTISONE

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

SUSPENSION/DROPS; OPHTHALMIC

CORTISPORIN

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

NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE

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

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

CREAM; TOPICAL

CORTISPORIN

> ADD >		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

> ADD >	BP	PAR PHARMACEUTICAL	50MG;0.125MG¤	N88907 001 SEP 20, 1985

IBUPROFEN (PAGE 3-120)

TABLET; ORAL

IBUPROFEN

> ADD >	AB	CHELSEA LABORATORIES	400MG¤	N70038 001 SEP 06, 1985
> ADD >	AB		600MG¤	N70041 001 SEP 06, 1985
> ADD >	AB	DANBURY PHARMACAL	400MG¤	N70436 001 AUG 21, 1985
> ADD >	AB		600MG¤	N70437 001 AUG 21, 1985
> ADD >	AB	MYLAN PHARMS	400MG¤	N70045 001 SEP 24, 1985
> ADD >	AB		600MG¤	N70057 001 SEP 24, 1985

IBUPROFEN (PAGE 3-120)

TABLET; ORAL

IBUPROFEN

> ADD >	AB	◑ PAR PHARMACEUTICALS	300MG¤	N70328 001 AUG 06, 1985
> ADD >	AB		400MG¤	N70329 001 AUG 06, 1985
> ADD >	AB		600MG¤	N70330 001 AUG 06, 1985

IBUPROHM

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

MOTRIN

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

INDOMETHACIN (PAGE 3-122)

CAPSULE; ORAL

INDOMETHACIN

> ADD >	AB	MYLAN PHARMS	50MG¤	N70624 001 SEP 04, 1985

LORAZEPAM (PAGE 3-132)

TABLET; ORAL

ATIVAN

> ADD >	AB	WYETH LABS/AMHO	0.5MG	N17794 001
> ADD >	AB		1MG	N17794 002
> ADD >	AB		2MG	N17794 003

LORAZEPAM

> ADD >	AB	QUANTUM PHARMICS	0.5MG¤	N70200 001 AUG 09, 1985
> ADD >	AB		1MG¤	N70201 001 AUG 09, 1985
> ADD >	AB		2MG¤	N70202 001 AUG 09, 1985

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

TABLET; ORAL

MECLIZINE HCL

> ADD >	AA	SUPERPHARM	12.5MG¤	N89113 001 AUG 20, 1985
> ADD >	AA		25MG¤	N89114 001 AUG 20, 1985

NITROGLYCERIN (PAGE 3-154)

INJECTABLE; INJECTION
NITROGLYCERIN

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

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

CREAM; TOPICAL
> ADD > MYCO-TRIACET II

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

POTASSIUM CHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

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

> ADD > POTASSIUM CITRATE (PAGE 3-173)

> ADD > TABLET; ORAL
> ADD > POTASSIUM CITRATE

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

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

SYRUP; ORAL
PROMETHAZINE

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

TABLET; ORAL
PROMETHAZINE HCL

> ADD >	BP	LEMMON	25MG*	N89109 001	
> ADD >				SEP 10, 1985	

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL
PROPRANOLOL HCL

> ADD >	AB	DURAMED PHARMS	10MG*	N70306 001	
> ADD >				SEP 09, 1985	
> ADD >	AB		20MG*	N70307 001	
> ADD >				SEP 09, 1985	
> ADD >	AB		40MG*	N70308 001	
> ADD >				SEP 09, 1985	
> ADD >	AB		80MG*	N70310 001	
> ADD >				SEP 09, 1985	

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL
PROPRANOLOL HCL

> ADD >	AB	MARTEC PHARMS	10MG*	N70120 001	
> ADD >				AUG 06, 1985	
> ADD >	AB		20MG*	N70121 001	
> ADD >				AUG 06, 1985	
> ADD >	AB		40MG*	N70122 001	
> ADD >				AUG 06, 1985	
> ADD >	AB		80MG*	N70124 001	
> ADD >				AUG 06, 1985	

> ADD > SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-191)

> ADD > GRANULE, EFFERVESCENT; ORAL
> ADD > BAROS

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

SODIUM CHLORIDE (PAGE 3-191)

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD >	AP	ABBOTT LABORATORIES	900MG/100ML*	N19480 001	
> ADD >				SEP 17, 1985	

> ADD > SULCONAZOLE NITRATE (PAGE 3-197)

> ADD > SOLUTION; TOPICAL
> ADD > SULCOSYN

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

> ADD >	AB	SIDMAK LABORATORIES	400MG;80MG*	N70215 001	
> ADD >				JUN 02, 1987 : SEP 10, 1985	
> ADD >	AB		800MG;160MG*	N70216 001	
> ADD >				JUN 02, 1987 : SEP 10, 1985	

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

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

> ADD > SULFAMETHOXAZOLE AND TRIMETHOPRIM SINGLE STRENGTH

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

> ADD > SULFANILAMIDE (PAGE 3-199)

> ADD > CREAM; VAGINAL
> ADD > VAGITROL
> ADD > LEMMON 15%M N88718 001
> ADD > SEP 19, 1985

SULFINPYRAZONE (PAGE 3-200)

CAPSULE; ORAL
SULFINPYRAZONE
> ADD > AB PAR PHARMACEUTICAL 200MGM N88934 001
> ADD > SEP 06, 1985

TABLET; ORAL
SULFINPYRAZONE
> ADD > AB PAR PHARMACEUTICAL 100MGM N88933 001
> ADD > SEP 06, 1985

THEOPHYLLINE (PAGE 3-206)

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

TABLET; ORAL
> ADD > QUIBRON-T
> ADD > MEAD JOHNSON/B-M 300MGM N88656 001
> ADD > AUG 22, 1985

> ADD > TABLET, CHEWABLE; ORAL
> ADD > THEOPHYL
> ADD > MCNEIL PHARM 100MGM N86506 001
> ADD > SEP 12, 1985

TROPICAMIDE (PAGE 3-219)

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

WARFARIN SODIUM (PAGE 3-221)

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

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

>ADD> INJECTABLE; INJECTION
>ADD> HUMULIN L
>ADD> ELI LILLY 100 UNITS/ML* N19377 002
>ADD> SEP 30, 1935

DRUG PRODUCTS APPROVED UNDER SECTION 505 OF THE ACT / **CUMULATIVE SUPPLEMENT NUMBER 1 / AUG'85 & SEP'85**
BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST

NO SEPTEMBER 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

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
325; 50mg
650; 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
325; 50mg
650; 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
1. Allopurinol	Jul 15, 1985
2. Amiloride Hydrochloride	Mar 29, 1985
3. Aminophylline Suppositories	Jul 05, 1983
4. Amitriptyline Hydrochloride	Jul 05, 1983
5. Anticholinergic Drugs (Controlled Release)	Nov 07, 1980
6. Carbamazepine	Dec 05, 1984
7. Chlordiazepoxide Hydrochloride	Jul 05, 1983
8. Chlorpropamide	Jul 05, 1983
9. Chlorthalidone	Jul 05, 1983
10. Clonidine Hydrochloride	Dec 05, 1984
11. Diazepam (revised)	Jul 08, 1985
12. Dicyclomine Hydrochloride	Aug 10, 1984
13. Dipyridamole	Jul 05, 1983
14. Disopyramide Phosphate	Jul 09, 1985
15. Dissolution Testing (General)	Apr 19, 1983
16. Doxepin Hydrochloride	Apr 02, 1985
17. Erythromycin	Apr 05, 1977
18. Hydrochlorothiazide	Jul 25, 1983
19. Hydroxyzine Hydrochloride (Dissolution Only)	Jan 27, 1981
20. Hydroxyzine Pamoate	Jul 26, 1983

(continued)

APPENDIX 3

(continued)

Name of Drug	Date
21. Indomethacin	Apr 06, 1985
22. Lorazepam	Dec 03, 1984
23. Methyltestosterone	Nov 16, 1979
24. Metoclopromide	Dec 27, 1984
25. Phentermine Hydrochloride (Dissolution)	Nov 21, 1980
26. Phentermine Hydrochloride (Slow Dissolving; Dissolution)	Nov 21, 1980
27. Phenylbutazone & Oxyphenbutazone	Jul 26, 1983
28. Prednisone (Dissolution Only)	Jul 10, 1985
29. Probenecid	Jul 26, 1983
30. Procainamide	Jul 25, 1983
31. Propranolol	May 19, 1984
32. Quinidine Gluconate (Controlled Release)	Jun 15, 1981
33. Spironolactone	Jul 25, 1983
34. Sulfinpyrazone	Jul 15, 1983
35. Theophylline (Controlled Release)	Apr 1984
36. Theophylline (Immediate Release)	Nov 02, 1983
37. Tolazamide	Aug 22, 1984
38. Tolbutamide	Jan 1982
39. Verapamil	Jul 1985
40. Temazepam	Aug 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 (Petitions Approved) and (2) is not suitable for submission as an ANDA (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
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

(continued)

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
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
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
Procainamide Hydrochloride Tablet; Oral	375mg	85 P-0125/CP	New Strength	Approved Sep 19, 1985
Propranolol Hydrochloride Solution; Oral	40mg/5ml	85 P-0073/CP	New Dosage Form	Approved Jul 8, 1985
Propranolol Hydrochloride Concentrate; Oral	80mg/ml	85 P-0073/ CP0002	New Dosage Form	Approved Jul 19, 1985
Propranolol Hydrochloride Solution; Oral	20mg/5ml	85 P-0073/ CP0003	New Dosage Form	Approved Sep 24, 1985
Propranolol Hydrochloride Tablet, Constant-Release; Oral	160mg	85 P-0129/CP	New Dosage Form	Approved Sep 25, 1985

(continued)

APPENDIX 4

I. Petitions Approved

(continued)

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

APPENDIX 4

II. Petitions Denied

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

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 30mg	85 P-0101/CP	New Combination	Denied Sep 11, 1985
Aspirin; Butalbital; Caffeine; Codeine Phosphate Capsule; Oral	325mg 50mg 40mg 60mg	85 P-0101/CP	New Combination	Denied Sep 11, 1985
Bretylium Tosylate Injectable; Injection	2mg/ml	85 P-0063/CP	New Strength	Denied May 29, 1985
Bretylium Tosylate Injectable; Injection	4mg/ml	85 P-0063/CP 0002	New Strength	Denied May 29, 1985
Bretylium Tosylate Injectable; Injection	8mg/ml	85 P-0063/CP 0003	New Strength	Denied May 29, 1985
Bretylium Tosylate Injectable; Injection	10mg/ml	85 P-0063/CP 0004	New Strength	Denied May 29, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
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
Heparin Sodium Injectable; Injection	2000 Units/ml	85 P-0065/CP	New Strength	Denied May 29, 1985
Heparin Sodium Injectable; Injection	4000 Units/ml	85 P-0065/CP	New Strength	Denied May 29, 1985
Ibuprofen; Oxycodone Hydrochloride Capsule; Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985
Ibuprofen; Oxycodone Hydrochloride Tablet; Oral	200mg 5mg	85 P-0141/CP	New Combination	Denied Sep 27, 1985
Indomethacin Tablet, Constant Release; Oral	75mg	85 P-0026/CP	New Dosage Form	Denied Sep 16, 1985

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

Drug Name Dosage Form, Route	Strength	Docket Number	Reason for Petition	Status
Metoclopramide Hydrochloride Injectable; Injection	10mg/ml	85 P-0062/CP	New Strength	Denied May 29, 1985
Metoclopramide Hydrochloride Injectable; Injection	20mg/ml	85 P-0062/CP/ 0002	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 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)
>ADD>	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)

INDICATIONS

	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
>DLT>	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
>ADD>	I-35	ANGINA PECTORIS DUE TO CORONARY ATHEROSCLEROSIS
>ADD>	I-36	ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY

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 ACTIONS

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
> ADD >	12365 005	4534973	AUG 13, 2002		
> ADD >	12366 002	4534974	AUG 13, 2002		
> DLT >	/16273 001/	/4324779/	/APR 13, 1999/		
> DLT >	/16273 002/	/4324779/	/APR 13, 1999/		
> DLT >	/16273 003/	/4324779/	/APR 13, 1999/		
> DLT >	/16363 001/	/4324779/	/APR 13, 1999/		
> ADD >	16636 002			D-9	SEP 24, 1986
				D-10	
				D-11	
				I-33	
> ADD >	16983 001			I-36	SEP 09, 1988
> ADD >	16990 001	3634582	JAN 11, 1989		
		3860618	JAN 14, 1992		
> DLT >	17560 001	RE28636	JUN 02, 1987	/I-21/	/SEP 24, 1986/
> DLT >	17560 002	RE28636	JUN 02, 1987	/I-21/	/SEP 24, 1986/
> DLT >	17581 001	3998966	DEC 21, 1993	/NS/	/SEP 24, 1986/
> ADD >	17760 001			NDF	SEP 04, 1988
> DLT >	/17688 001/	/4324779/	/APR 13, 1999/		
> ADD >	17768 001	3855140	DEC 17, 1991		
		3960745	DEC 17, 1991		
> ADD >	17970 001	4536516	AUG 20, 2002		
> DLT >	/18154 001/	/3461461/	/AUG 12, 1986/		
> ADD >	18154 001	3461461	MAY 07, 1985		
> DLT >	/18154 003/	/3461461/	/AUG 12, 1986/		
> ADD >	18154 003	3461461	MAY 07, 1985		
> ADD >	18240 001			I-35	SEP 04, 1988
> ADD >	18240 002			I-35	SEP 04, 1988
> ADD >	18423 001	3855140	DEC 17, 1991		
		3960745	DEC 17, 1991		
> ADD >	18482 001	3784684	JAN 08, 1991		
> ADD >	18509 001			NP	AUG 07, 1988
> ADD >	18513 002			ODE	JUL 28, 1990

APPENDIX 6

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

	APPL/PROD	PATENT NUMBER	PATENT EXPIRES	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
>_ADD_>	18738 001	4055652	OCT 25, 1994	NCE	AUG 30, 1990
>_ADD_>	18928 001	4221778	SEP 09, 1997		
>_ADD_>	19071 001			ODE	AUG 30, 1992
				NP	AUG 30, 1988
>_ADD_>	19011 001			NP	SEP 24, 1986
>_ADD_>	19259 001	3980778	SEP 14, 1993		
>_ADD_>	19260 001	3980778	SEP 14, 1993		
>_ADD_>	19264 001			ODE	OCT 16, 1991
>_ADD_>	19270 001	4252984	FEB 24, 1998	NCE	AUG 30, 1990
		4311708	JAN 19, 1999		
		4342783	AUG 03, 1999		

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			$