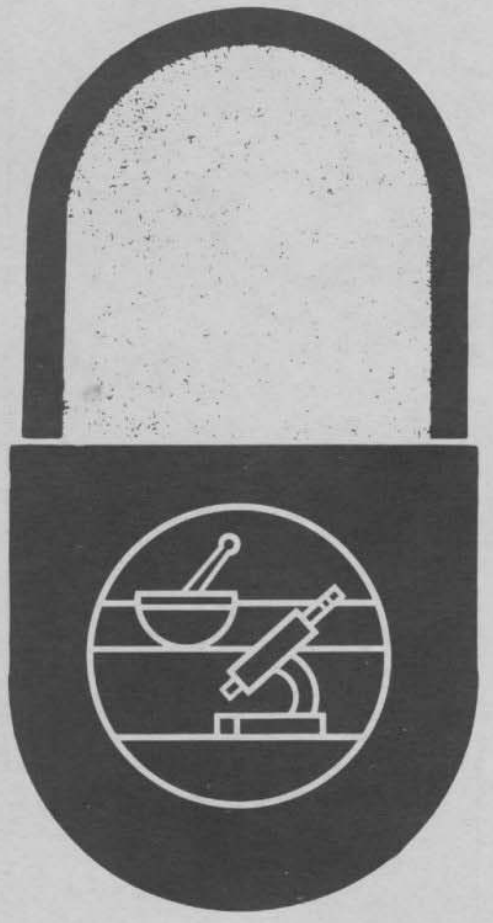
CUMULATIVE
SUPPLEMENT 1
JAN'87



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

7TH 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

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1.0 INTRODUCTION

1.1 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, 7th Edition (the List). The List is composed of three parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, and drug products approved by the Division of Blood and Blood Products under Section 505 of the Act.

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. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products Approved Under Section 505 of the Act by the Division of Blood and Blood Products lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the left of the active ingredient name for each product, along with the application number and product number (FDA's internal file number). All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section for an explanation of the use codes and exclusivity abbreviations.

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

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the list will not be repeated for context.] The effective (marketing) date (the date a product may be marketed), when appropriate, will appear to the left of the approval date.

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.)

Additions new to the List and the Patent and Exclusivity Information Addendum are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (◆) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the List and the Patent and Exclusivity Information Addendum are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print will remain in all Cumulative Supplements for this edition.

Products discontinued from marketing or that have had their application withdrawn, for other than safety or effectiveness reasons, will be flagged in this Cumulative Supplement with the " ə " symbol to designate their non-marketed status. All products having a " ə " symbol in the 12th Cumulative Supplement of the 7th Edition will then be added to the "Discontinued Drug Products List" appearing in the 8th Edition.

1.2 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 tablet 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 tablet 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, C_{max}, T_{max}) 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 Section 3.7 of the 7th Edition for available guidance from the Division of Bioequivalence.)

1.3 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).

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

1.4 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
Nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (ointment;topical)	SEP 3, 1986 (51 FR 31371)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
Tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

1.5 GAVISCON

Gaviscon is an over-the-counter (OTC) product which has been marketed since September 1970. The active ingredients, aluminum hydroxide and magnesium trisilicate, for this product were reviewed by the OTC Antacid Panel and were considered to be safe and effective ingredients (Category I) by that panel. However, the tablet failed to pass the antacid test which is required of all antacid products; therefore, it was placed in Category III for lack of effectiveness and a full NDA was required to be submitted by the firm. The firm's NDA was approved December 9, 1983. Gaviscon's activity in treating reflex acidity is made possible by the inactive ingredients, sodium bicarbonate and alginic acid, in the amounts used in Gaviscon. Therefore, all ANDAs which cite Gaviscon as the listed drug must contain the inactive ingredients, sodium bicarbonate and alginic acid.

1.6 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 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.

1.7 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The counts appear in two sections. Section A. provides baseline and quarterly data. The baseline column refers to the products in the List. For each three-month period following December '86, 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	DEC '86 (BASELINE)
DRUG PRODUCTS LISTED	8957
SINGLE SOURCE	2103 (23.5%)
MULTISOURCE(1)	6854 (76.5%)
THERAPEUTICALLY EQUIVALENT	5838 (65.2%)
NOT THERAPEUTICALLY EQUIVALENT	967 (10.8%)
EXCEPTIONS(2)	49 (0.5%)
NEW MOLECULAR ENTITIES APPROVED	-
NUMBER OF APPLICANTS	333

B. ACTIVITY FOR SUPPLEMENT NUMBER 1

	JAN '87	CUMULATIVE
DRUG PRODUCTS ADDED:	83	83
NEWLY APPROVED	81	81
DESI EFFECTIVE	2	2
REMARKETED	0	0
DRUG PRODUCTS REMOVED:	0	0
WITHDRAWN APPROVAL	0	0
RX TO OTC SWITCH	0	0
NET GAIN IN DRUG PRODUCTS	83	83
SINGLE SOURCE PRODUCTS APPROVED	12	12
MULTISOURCE DRUG PRODUCTS APPROVED	71	71
NEW MOLECULAR ENTITIES APPROVED:	1	1
AS THE ENTITY	1	1
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	0

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

(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 1-8 OF THE LIST)

x

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

>ADD>		BUTALBITAL, ACETAMINOPHEN AND CAFFEINE			
>ADD>	AB	MIKART	325MG;50MG;40MG¤	N89175 001	
>ADD>				JAN 21, 1987	

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

		PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN			
>ADD>	AB	PUREPAC/KALIPHARMA	650MG;100MG¤	N70910 001	
>ADD>				JAN 02, 1987	
>ADD>	AB	SUPERPHARM	650MG;100MG¤	N71319 001	
>ADD>				JAN 06, 1987	

ALBUTEROL SULFATE

SOLUTION; INHALATION

>ADD>		PROVENTIL			
>ADD>		SCHERING	EQ 0.083% BASE¤	N19243 002	
>ADD>				JAN 14, 1987	
>ADD>	AN		EQ 0.5% BASE¤	N19243 001	
>ADD>				JAN 14, 1987	
>ADD>		VENTOLIN			
>ADD>	AN	GLAXO	EQ 0.5% BASE¤	N19269 002	
>ADD>				JAN 16, 1987	

ALLOPURINOL

TABLET; ORAL

		ALLOPURINOL			
>ADD>	AB	MUTUAL PHARM	100MG¤	N71449 001	
>ADD>				JAN 09, 1987	
>ADD>	AB		300MG¤	N71450 001	
>ADD>				JAN 09, 1987	

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

		AMANTADINE HCL			
>ADD>	AB	BOLAR PHARMACEUTICAL	100MG¤	N71382 001	
>ADD>				JAN 21, 1987	

AMPICILLIN SODIUM

INJECTABLE; INJECTION

		AMPICILLIN SODIUM			
>ADD>	AP	INTL MEDICATION SYS	EQ 1GM BASE/VIAL	N62634 002	
>ADD>				JAN 09, 1987	
>ADD>	AP		EQ 2GM BASE/VIAL	N62634 003	
>ADD>				JAN 09, 1987	

ATROPINE

INJECTABLE; INJECTION

		ATROPEN			
>ADD>	AP	SURVIVAL TECHNOLOGY	EQ 2MG SULFATE/0.7ML	N17106 001	
>ADD>		ATROPINE			
>ADD>	AP	KALI-DUPHAR LABS	EQ 2MG SULFATE/0.7ML¤	N71295 001	
>ADD>				JAN 30, 1987	

CARBAMAZEPINE

TABLET; ORAL

		CARBAMAZEPINE			
>ADD>	AB	PARKE-DAVIS/W-L	200MG¤	N70429 001	
>ADD>				JAN 02, 1987	

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

		CLAFORAN			
>ADD>		AM HOECHST	EQ 1GM BASE/VIAL¤	N62659 001	
>ADD>				JAN 13, 1987	
>ADD>			EQ 2GM BASE/VIAL¤	N62659 002	
>ADD>				JAN 13, 1987	

CEFOXITIN SODIUM

INJECTABLE; INJECTION

		MEFOXIN			
>ADD>		MS&D	EQ 1GM BASE/VIAL¤	N62757 001	
>ADD>				JAN 08, 1987	
>ADD>			EQ 2GM BASE/VIAL¤	N62757 002	
>ADD>				JAN 08, 1987	

CEPHALEXIN

CAPSULE; ORAL

> ADD >		**CEPHALEXIN MONOHYDRATE**			
> ADD >	AB	VITARINE	EQ 250MG BASE¤		N62159 001
> ADD >	AB		EQ 500MG BASE¤		N62159 002
		KEFLEX			
> ADD >	AB	ELI LILLY	EQ 250MG BASE		N50405 002
> ADD >	AB		EQ 250MG BASE		N62118 001
> ADD >	AB		EQ 500MG BASE		N50405 003
> ADD >	AB		EQ 500MG BASE		N62118 002

CEPHRADINE

CAPSULE; ORAL

> ADD >		**CEPHRADINE**			
> ADD >	AB	BIOCRAFT LABS	250MG¤		N62683 001
> ADD >					JAN 09, 1987
> ADD >	AB		500MG¤		N62683 002
> ADD >					JAN 09, 1987

POWDER FOR RECONSTITUTION; ORAL

> ADD >		**CEPHRADINE**			
> ADD >	AB	BIOCRAFT LABS	125MG/5ML¤		N62693 001
> ADD >					JAN 09, 1987
> ADD >	AB		250MG/5ML¤		N62693 002
> ADD >					JAN 09, 1987

CILASTATIN SODIUM; IMIPENEM

INJECTABLE; INJECTION

		PRIMAXIN			
> ADD >		MS&D	EQ 250MG BASE/VIAL;		
> ADD >			250MG/VIAL¤		N62756 001
> ADD >					JAN 08, 1987
> ADD >			EQ 500MG BASE/VIAL;		
> ADD >			500MG/VIAL¤		N62756 002
> ADD >					JAN 08, 1987

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL

> ADD >		CLEOCIN T			
> ADD >		UPJOHN	EQ 1% BASE¤		N50615 001
> ADD >					JAN 07, 1987

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

> ADD >		**CLORAZEPATE DIPOTASSIUM**			
> ADD >	AB	AM THERAPEUTICS	3.75MG¤		N71429 001
> ADD >				JUN 23, 1987 :	JAN 08, 1987
> ADD >	AB		7.5MG¤		N71430 001
> ADD >				JUN 23, 1987 :	JAN 08, 1987
> ADD >	AB		15MG¤		N71431 001
> ADD >				JUN 23, 1987 :	JAN 08, 1987
		TRANXENE			
> ADD >	AB	ABBOTT LABS	3.75MG		N17105 001
> ADD >	AB		7.5MG		N17105 002
> ADD >	AB		15MG		N17105 003

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

		DIPHENHYDRAMINE HCL			
> ADD >	AA	MUTUAL PHARM	25MG¤		N89488 001
> ADD >					JAN 02, 1987
> ADD >	AA		50MG¤		N89489 001
> ADD >					JAN 02, 1987

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

		DISOPYRAMIDE PHOSPHATE			
> ADD >	AB	INTERPHARM	EQ 100MG BASE¤		N71190 001
> ADD >					JAN 15, 1987
> ADD >	AB		EQ 150MG BASE¤		N71191 001
> ADD >					JAN 15, 1987

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

> ADD >		**GYNEX 0.5/35E-21**			
> ADD >	AB	GYNEX LABS	0.035MG;0.5MG¤		N70684 001
> ADD >					JAN 29, 1987
> ADD >		**GYNEX 1/35E-21**			
> ADD >	AB	GYNEX LABS	0.035MG;1MG¤		N70685 001
> ADD >					JAN 29, 1987

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

>ADD>		GYNEX 0.5/35E-28			
>ADD>	AB	GYNEX LABS	0.035MG;0.5MG¤	N70686 001	JAN 29, 1987
>ADD>					
>ADD>		GYNEX 1/35E-28			
>ADD>	AB	GYNEX LABS	0.035MG;1MG¤	N70687 001	JAN 29, 1987
>ADD>					

FLUOROURACIL

INJECTABLE; INJECTION

		FLUOROURACIL			
>ADD>	AP	LYPHOMED	50MG/ML¤	N89428 001	JAN 12, 1987
>ADD>					

FUROSEMIDE

INJECTABLE; INJECTION

		FUROSEMIDE			
>ADD>	AP	CARTER-GLOGAU LABS	10MG/ML¤	N70604 001	JAN 02, 1987
>ADD>					

TABLET; ORAL

		FUROSEMIDE			
>ADD>	AB	WATSON LABS	20MG¤	N71379 001	JAN 02, 1987
>ADD>					

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

		GENTAMICIN SULFATE			
>ADD>	AT	MAURRY BIOLOGICAL	EQ 3MG BASE/ML¤	N62635 001	JAN 08, 1987
>ADD>					

HALOPERIDOL

TABLET; ORAL

		HALOPERIDOL			
>ADD>	AB	BARR LABORATORIES	0.5MG¤	N71156 001	JAN 02, 1987
>ADD>					
>ADD>	AB		1MG¤	N71157 001	JAN 02, 1987
>ADD>					
>ADD>	AB		2MG¤	N71172 001	JAN 02, 1987
>ADD>					

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

		HALDOL			
>ADD>	AP	MCNEIL LABORATORIES	EQ 5MG BASE/ML	N15923 001	
		HALOPERIDOL			
>ADD>	AP	LYPHOMED	EQ 5MG BASE/ML¤	N71187 001	JAN 20, 1987
>ADD>					
>ADD>	AP	QUAD PHARMS	EQ 5MG BASE/ML¤	N71082 001	JAN 07, 1987
>ADD>					

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION

		HYDROXYPROGESTERONE CAPROATE			
>ADD>	AO	QUAD PHARMS	125MG/ML¤	N89330 001	JAN 02, 1987
>ADD>					
>ADD>	AO		250MG/ML¤	N89331 001	JAN 02, 1987
>ADD>					

HYDROXYZINE PAMOATE

CAPSULE; ORAL

		HYDROXYZINE PAMOATE			
>ADD>	AB	SUPERPHARM	EQ 25MG HCL¤	N89031 001	JAN 02, 1987
>ADD>					
>ADD>	AB		EQ 50MG HCL¤	N89032 001	JAN 02, 1987
>ADD>					
>ADD>	AB		EQ 100MG HCL¤	N89033 001	JAN 02, 1987
>ADD>					

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

		LEUCOVORIN CALCIUM			
>ADD>	AP	ELKINS-SINN/AHROBINS	EQ 50MG BASE/VIAL¤	N70480 001	JAN 02, 1987
>ADD>					

POWDER FOR RECONSTITUTION; ORAL

>ADD>		LEUCOVORIN CALCIUM			
>ADD>		LEDERLE LABS/AM CYAN	EQ 60MG BASE/VIAL¤	N08107 003	JAN 30, 1987
>ADD>					

MANNITOL

INJECTABLE; INJECTION

>ADD>		MANNITOL 5% IN PLASTIC CONTAINER			
>ADD>	AP	ABBOTT LABS	5GM/100ML¤	N19603 001	JAN 08, 1987
>ADD>					
>ADD>		MANNITOL 10% IN PLASTIC CONTAINER			
>ADD>	AP	ABBOTT LABS	10GM/100ML¤	N19603 002	JAN 08, 1987
>ADD>					

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
ANTIVERT

>ADD>		ROERIG/PFIZER	50MG	N10721 001	
>ADD>				JAN 20, 1982	

METHYLDOPA

TABLET; ORAL
METHYLDOPA

>ADD>	AB	PAR PHARMACEUTICAL	125MG¤	N70535 001	
>ADD>				JAN 02, 1987	
>ADD>	AB		250MG¤	N70536 001	
>ADD>				JAN 02, 1987	
>ADD>	AB		500MG¤	N70537 001	
>ADD>				JAN 02, 1987	

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION
METHYLDOPATE HCL

>ADD>	AP	SOLOPAK LABORATORIES	50MG/ML¤	N70841 001	
>ADD>				JAN 02, 1987	

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION
MEZLIN

>ADD>		MILES PHARMS/MILES	EQ 3GM BASE/VIAL¤	N62697 001	
>ADD>				JAN 22, 1987	
>ADD>			EQ 4GM BASE/VIAL¤	N62697 002	
>ADD>				JAN 22, 1987	

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL

>ADD>	AP	ABBOTT LABS	0.02MG/ML¤	N70252 001	
>ADD>				JAN 16, 1987	
>ADD>	AP		0.02MG/ML¤	N70253 001	
>ADD>				JAN 16, 1987	
>ADD>	AP		0.4MG/ML¤	N70254 001	
>ADD>				JAN 07, 1987	
>ADD>	AP		0.4MG/ML¤	N70255 001	
>ADD>				JAN 07, 1987	
>ADD>	AP		0.4MG/ML¤	N70256 001	
>ADD>				JAN 07, 1987	
>ADD>	AP		0.4MG/ML¤	N70257 001	
>ADD>				JAN 07, 1987	

NITROGLYCERIN

INJECTABLE; INJECTION
NITROSTAT

>ADD>	AP	PARKE-DAVIS/W-L	5MG/ML¤	N70863 001	
>ADD>				JAN 08, 1987	
>ADD>			10MG/ML¤	N70871 001	
>ADD>				JAN 08, 1987	
>ADD>			10MG/ML¤	N70872 001	
>ADD>				JAN 08, 1987	

OXAZEPAM

TABLET; ORAL
OXAZEPAM

>ADD>	AB	BARR LABORATORIES	15MG¤	N70683 001	
>ADD>				JAN 16, 1987	

SERAX

>ADD>	AB	WYETH	15MG	N15539 008	

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

>ADD>	AP	CARTER-GLOGAU LABS	2MEQ/ML¤	N89421 001	
>ADD>				JAN 02, 1987	

PROCAINAMIDE HYDROCHLORIDE

TABLET, CONTROLLED RELEASED; ORAL
PROCAINAMIDE HCL

>ADD>	AB	BOLAR PHARMACEUTICAL	1GM¤	N89520 001	
>ADD>				JAN 15, 1987	
>ADD>	AB	CORD LABORATORIES	500MG¤	N89370 001	
>ADD>				JAN 09, 1987	

PROCAN SR

>ADD>	AB	PARKE-DAVIS/W-L	1GM	N88489 001	
				JAN 16, 1985	

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCHLORPERAZINE MALEATE

>ADD>	AB	DURAMED PHARMS	EQ 5MG BASE¤	N89484 001	
>ADD>				JAN 20, 1987	
>ADD>	AB		EQ 10MG BASE¤	N89485 001	
>ADD>				JAN 20, 1987	
>ADD>	AB		EQ 25MG BASE¤	N89486 001	
>ADD>				JAN 20, 1987	

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL
> ADD > AB CHELSEA LABORATORIES 60MG¤ N70143 001
> ADD > JAN 15, 1987

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
> ADD > SULFAMETHOXAZOLE AND TRIMETHOPRIM
> ADD > AP LYPHOMED 80MG/ML;16MG/ML¤ N70223 001
> ADD > DEC 29, 1987 : JAN 16, 1987

SULFANILAMIDE

CREAM; VAGINAL
> ADD > AVC
> ADD > AT MERRELL DOW/DOW CHEM 15%¤ N06530 003
> ADD > JAN 27, 1987
VAGITROL
> ADD > AT LEMMON 15% N88718 001
SEP 19, 1985

> ADD > SUPPOSITORY; VAGINAL
> ADD > AVC
> ADD > MERRELL DOW/DOW CHEM 1.05GM¤ N06530 004
> ADD > JAN 27, 1987

> ADD > TECHNETIUM TC-99M, MEBROFENIN KIT

> ADD > INJECTABLE; INJECTION
> ADD > CHOLETEC
> ADD > SQUIBB DIAGNOSTICS N/A¤ N18963 001
> ADD > JAN 21, 1987

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL

>ADD>	BROMPHERIL			
>ADD>	COPLEY PHARM	6MG;120MG¤	N89116 001	
>ADD>			JAN 22, 1987	

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL

>ADD>	VICKS FORMULA 44			
>ADD>	VICKS HLTH CARE	12.5MG/5ML¤	N70524 001	
>ADD>			JAN 14, 1987	

IBUPROFEN

TABLET; ORAL

>ADD>	NEUVIL			
>ADD>	LUCHEM PHARMS	200MG¤	N71144 001	
>ADD>			JAN 20, 1987	

POVIDONE-IODINE

SPONGE; TOPICAL

>ADD>	E-Z SCRUB 241			
>ADD>	DESERET	10%¤	N19476 001	
>ADD>			JAN 07, 1987	

NO JANUARY 1987 APPROVALS

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG". SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

ORPHAN DRUG EXCLUSIVE APPROVAL STATUS (CODED ODE) APPLIES ONLY TO THE APPROVED OR LICENSED INDICATION(S) FOR WHICH ORPHAN DRUG DESIGNATION HAS BEEN GRANTED PURSUANT TO SECTION 526 OF THE ACT.

FOR THE FOLLOWING DRUG PRODUCTS WITH ORPHAN DRUG EXCLUSIVE APPROVAL STATUS, THE SPONSOR HAS SEVEN YEARS OF EXCLUSIVE APPROVAL FOR THE APPROVED INDICATION BEGINNING ON THE DATE OF NDA, ANTIBIOTIC APPLICATION, OR BIOLOGICAL LICENSE APPROVAL FOR THE DRUG. NO SUBSEQUENT SPONSOR MAY RECEIVE APPROVAL OF AN NDA, BIOLOGICAL LICENSE, PAPER NDA, ANTIBIOTIC APPLICATION, ANDA, OR ABBREVIATED ANTIBIOTIC APPLICATION DURING THE SEVEN YEAR PERIOD FOR THE DRUG AND INDICATION(S) FOR WHICH A PERSON MAINTAINS ODE STATUS UNLESS THE EXCLUSIVE APPROVAL HAS BEEN REVOKED AS DESCRIBED ABOVE OR THE SUBSEQUENT SPONSOR HAS OBTAINED WRITTEN CONSENT FROM THE SPONSOR WHO HAS RECEIVED EXCLUSIVE APPROVAL.

BIOLOGICAL PRODUCTS, ANTIBIOTICS, AND DRUGS THAT HAVE BEEN APPROVED UNDER SECTION 505 OR 507 OF THE ACT OR UNDER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT FOR MARKETING AND HAVE BEEN GIVEN ORPHAN DRUG EXCLUSIVE APPROVAL WILL BE NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY DATA APPENDIX. DRUG PRODUCTS THAT HAVE RECEIVED THE WRITTEN PERMISSION OF THE SPONSOR THAT HAS ORPHAN DRUG EXCLUSIVE APPROVAL TO BE APPROVED UNDER SECTION 527(B)(2) OF THE ACT ARE ALSO NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY DATA APPENDIX. THESE DRUG PRODUCTS DO NOT HAVE ANY EXCLUSIVE APPROVAL RIGHTS OF THEIR OWN, BUT CAN BE MARKETED BECAUSE OF THE CONSENT GIVEN BY THE SPONSOR THAT HAS EXCLUSIVE APPROVAL. THESE PRODUCTS ARE MARKED BY AN (*) NEXT TO THE APPLICANT'S NAME.

DRUG PRODUCTS

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME DOSAGE FORM; ROUTE	APPLICANT	APPLICATION NUMBER APPROVAL DATE	EXCLUSIVITY EXP. DATE
CALCITONIN, HUMAN 0.5MG/VIAL	CIBACALCIN INJECTABLE; INJECTION	CIBA/CIBA-GEIGY	18470 001 OCT 31, 1986	ODE OCT 31, 1993

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

NO JANUARY 1987 ACTIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFN-250, ROOM 17B-06, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

NO JANUARY 1987 ACTIONS

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.

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
BRETYLIUM TOSYLATE INJECTABLE; INJECTION	200MG/ML (10ML/CONTAINER)	85 P-0546/CP	INTL MEDICATION SYS	NEW STRENGTH	APPROVED JAN 20, 1987
CHOLESTYRAMINE CAPSULE; ORAL	EQ 500MG RESIN	86 P-0474/CP	BRISTOL-MYERS	NEW DOSAGE FORM NEW STRENGTH	APPROVED JAN 30, 1987
CHOLESTYRAMINE TABLET; ORAL	EQ 800MG RESIN	86 P-0475/CP	BRISTOL-MYERS	NEW DOSAGE FORM NEW STRENGTH	APPROVED JAN 30, 1987
FLUOROURACIL INJECTABLE; INJECTION	50MG/ML (50ML/VIAL)	86 P-0490/CP	ADRIA LABORATORIES	NEW STRENGTH	APPROVED JAN 9, 1987
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 25MG BASE/VIAL	86 P-0240/CP	BURROUGHS WELLCOME	NEW STRENGTH	APPROVED JAN 29, 1987
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 100MG BASE/VIAL	86 P-0152/CP	BEN VENUE LABS	NEW STRENGTH	APPROVED JAN 20, 1987
LEUCOVORIN CALCIUM TABLET; ORAL	EQ 10MG BASE	86 P-0258/CP	LEDERLE LABS/AM CYAN	NEW STRENGTH	APPROVED JAN 16, 1987

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 7TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES

NEW INDICATION

ADD	I-54	CONTRAST ENHANCEMENT OF COMPUTED TOMOGRAPHIC BODY IMAGING
ADD	I-55	PEDIATRIC ANGIOCARDIOGRAPHY
ADD	I-56	INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY
ADD	I-57	PERIPHERAL VENOGRAPHY (PHLEBOGRAPHY)
ADD	I-58	EXCRETORY UROGRAPHY
ADD	I-59	ARTHROGRAPHY
ADD	I-60	HYSTEROSALPINGOGRAPHY
ADD	I-61	AORTOGRAPHY

EXCLUSIVITY TERMS

PATENT USE CODE

ADD	U-1	PREVENTION OF PREGNANCY
ADD	U-2	CYCLIC CONTROL
ADD	U-3	TREATMENT OF AMENORRHEA, DYSMENORRHEA, AND FUNCTIONAL UTERINE BLEEDING
ADD	U-4	TREATMENT OR PROPHYLAXIS OF ANGINA PECTORIS AND ARRHYTHMIA
ADD	U-5	TREATMENT OF HYPERTENSION
ADD	U-6	TREATING MAMMALS SUFFERING [FROM] ANXIETY
ADD	U-7	PROVIDING PREVENTION AND TREATMENT OF EMESIS AND NAUSEA IN MAMMALS
ADD	U-8	REDUCING INTRAVASCULAR PRESSURE IN MAMMALS
ADD	U-9	METHOD OF PRODUCING BRONCHODILATION
ADD	U-10	METHOD OF PRODUCING SYMPATHOMIMETIC EFFECTS
ADD	U-11	INCREASING CARDIAC CONTRACTILITY
ADD	U-12	TREATMENT OF BURNS
ADD	U-13	CONTROL OF EMESIS ASSOCIATED WITH ANY CANCER CHEMOTHERAPY AGENT
ADD	U-14	TREATMENT OF STRESS-INDUCED DEPRESSION
ADD	U-15	DIAGNOSTIC METHOD FOR DISTINGUISHING BETWEEN HYPOTHALMIC MALFUNCTIONS OR LESIONS IN HUMANS

	APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	18917 001	SECTRAL; ACEBUTOLOL HYDROCHLORIDE	3857952	DEC 31, 1993	U-4		
>ADD>	18917 003	SECTRAL; ACEBUTOLOL HYDROCHLORIDE	3857952	DEC 31, 1993	U-4		
>ADD>	19243 001	PROVENTIL; ALBUTEROL SULFATE	3644353	FEB 22, 1989		NDF	JAN 14, 1990
>ADD>			3705233	DEC 05, 1989			
>ADD>	19243 002	PROVENTIL; ALBUTEROL SULFATE	3644353	FEB 22, 1989		NDF	JAN 14, 1990
>ADD>			3705233	DEC 05, 1989			
>ADD>	19353 001	ALFENTA; ALFENTANIL HYDROCHLORIDE	4167574	SEP 11, 1996		NCE	DEC 29, 1991
>ADD>	18700 001	INOCOR; AMRINONE LACTATE	4072746	FEB 07, 1995	U-11		
>DLT>	19270 001	BETOPTIC; BETAXOLOL HYDROCHLORIDE	4252984	FEB 24, 1998		NCE	AUG 30, 1990
>ADD>	19270 001	BETOPTIC; BETAXOLOL HYDROCHLORIDE	4252984	JUL 31, 1999		NCE	AUG 30, 1990
>ADD>	18770 001	TORNALATE; BITOLTEROL MESYLATE	4336400	JUN 22, 1999	U-10		
>ADD>			4336400	JUN 22, 1999	U-9		
>DLT>	18644 001	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1992			
>ADD>	18644 001	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1994			
>DLT>	18644 002	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1992			
>ADD>	18644 002	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1994			
>DLT>	18644 003	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1992			
>ADD>	18644 003	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1994			
>DLT>	19215 001	FEMSTAT; BUTOCONAZOLE NITRATE	4078071	MAR 07, 1995		NCE	NOV 25, 1990
>ADD>	19215 001	FEMSTAT; BUTOCONAZOLE NITRATE	4078071	MAR 07, 1997		NCE	NOV 25, 1990
>ADD>	18470 001	CIBACALCIN; CALCITONIN, HUMAN				ODE	OCT 31, 1993
>DLT>	19322 001	TEMOVATE; CLOBETASOL PROPIONATE	3721687	MAR 20, 1990		NCE	DEC 27, 1990
>ADD>	19322 001	TEMOVATE; CLOBETASOL PROPIONATE	3721687	MAR 20, 1992		NCE	DEC 27, 1990
>DLT>	19323 001	TEMOVATE; CLOBETASOL PROPIONATE	3721687	MAR 20, 1990		NCE	DEC 27, 1990
>ADD>	19323 001	TEMOVATE; CLOBETASOL PROPIONATE	3721687	MAR 20, 1992		NCE	DEC 27, 1990
>ADD>	17820 002	DOBUTREX; DOBUTAMINE HYDROCHLORIDE	3987200	OCT 19, 1993	U-11		
>ADD>	16672 001	OVRAL; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		
>ADD>	16806 001	OVRAL-28; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		
>ADD>	17612 001	LO/OVRAL; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		
>ADD>	17802 001	LO/OVRAL-28; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		
>ADD>	18668 001	NORDETTE-21; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		

	APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	18782 001	NORDETTE-28; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		
>ADD>	19190 001	TRIPHASIL-28; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		
>ADD>			3957982	MAY 18, 1993	U-1		
>ADD>	19192 001	TRIPHASIL-21; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		
>ADD>			3957982	MAY 18, 1993	U-1		
>DLT>	18830/001	TAMBOCOR; FLECAINIDE ACETATE	4005209	JAN 25, 1994			
>ADD>	18830 001	TAMBOCOR; FLECAINIDE ACETATE	4005209	JAN 25, 1996			
>DLT>	18830/002//TAMBOCOR; FLECAINIDE ACETATE		4005209	JAN 25, 1994			
>ADD>	18830 002	TAMBOCOR; FLECAINIDE ACETATE	4005209	JAN 25, 1996			
>ADD>	19404 001	OCUFEN; FLURBIPROFEN SODIUM	3755427	AUG 28, 1990		NCE	DEC 31, 1991
>ADD>			3793457	FEB 19, 1991			
>ADD>	18123 001	FACTREL; GONADORELIN HYDROCHLORIDE	3947569	MAR 30, 1993	U-15		
>ADD>			4110438	AUG 29, 1995	U-14		
>ADD>	18123 002	FACTREL; GONADORELIN HYDROCHLORIDE	3947569	MAR 30, 1993	U-15		
>ADD>			4110438	AUG 29, 1995	U-14		
>ADD>	18123 003	FACTREL; GONADORELIN HYDROCHLORIDE	3947569	MAR 30, 1993	U-15		
>ADD>			4110438	AUG 29, 1995	U-14		
>ADD>	18587 001	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5		
>ADD>	18587 002	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5		
>ADD>	18587 003	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5		
>DLT>	18956 001	OMNIPAQUE 180; IOHEXOL	4250113	FEB 10, 1998		NCE	DEC 26, 1990
>ADD>	18956 001	OMNIPAQUE 180; IOHEXOL	4250113	DEC 26, 1999		NCE	DEC 26, 1990
>DLT>	18956 002	OMNIPAQUE 240; IOHEXOL	4250113	FEB 10, 1998		NCE	DEC 26, 1990
>ADD>	18956 002	OMNIPAQUE 240; IOHEXOL	4250113	DEC 26, 1999		NCE	DEC 26, 1990
>DLT>	18956 003	OMNIPAQUE 300; IOHEXOL	4250113	FEB 10, 1998		NCE	DEC 26, 1990
>ADD>	18956 003	OMNIPAQUE 300; IOHEXOL	4250113	DEC 26, 1999		NCE	DEC 26, 1990
>DLT>	18956 004	OMNIPAQUE 350; IOHEXOL	4250113	FEB 10, 1998		NCE	DEC 26, 1990
>ADD>	18956 004	OMNIPAQUE 350; IOHEXOL	4250113	DEC 26, 1999		NCE	DEC 26, 1990
>DLT>	18735 001	ISOVUE-M 200; IOPAMIDOL	4001323	JAN 04, 1994		NCE	DEC 31, 1990
>ADD>	18735 001	ISOVUE-M 200; IOPAMIDOL	4001323	JAN 04, 1996		NCE	DEC 31, 1990
>DLT>	18735 002	ISOVUE-300; IOPAMIDOL	4001323	JAN 04, 1994		NCE	DEC/31, 1990
>ADD>	18735 002	ISOVUE-300; IOPAMIDOL	4001323	JAN 04, 1996		NCE	DEC 31, 1990
>DLT>	18735 003	ISOVUE-370; IOPAMIDOL	4001323	JAN 04, 1994		NCE	DEC 31, 1990
>ADD>	18735 003	ISOVUE-370; IOPAMIDOL	4001323	JAN 04, 1996		NCE	DEC 31, 1990
>DLT>	18735 004	ISOVUE-M 300; IOPAMIDOL	4001323	JAN 04, 1994		NCE	DEC/31, 1990
>ADD>	18735 004	ISOVUE-M 300; IOPAMIDOL	4001323	JAN 04, 1996		NCE	DEC 31, 1990

	APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	13295 002	CONRAY-43; IOTHALAMATE MEGLUMINE				I-54	DEC 18, 1989
>ADD>	18905 002	HEXABRIX; IOXAGLATE MEGLUMINE				I-55	OCT 22, 1989
>ADD>						I-56	OCT 22, 1989
>ADD>						I-57	OCT 22, 1989
>ADD>						I-58	OCT 22, 1989
>ADD>						I-59	OCT 22, 1989
>ADD>						I-60	OCT 22, 1989
>ADD>						I-61	OCT 22, 1989
>ADD>			4065553	DEC 27, 1994		I-6	OCT 22, 1989
>ADD>			4065554	DEC 27, 1994		I-36	OCT 22, 1989
>ADD>			4094966	JUN 13, 1995		I-54	OCT 22, 1989
>DLT>			4014986	MAR 29, 1994		NCE	JUL 26, 1990
>ADD>			4014986	MAR 29, 1996		NCE	JUL 26, 1990
>DLT>	18754 002	ORUDIS; KETOPROFEN	3641127	FEB 08, 1989		NCE	JAN 09, 1991
>ADD>	18754 002	ORUDIS; KETOPROFEN	3641127	FEB 08, 1991		NCE	JAN 09, 1991
>DLT>	18754 003	ORUDIS; KETOPROFEN	3641127	FEB 08, 1989		NCE	JAN 09, 1991
>ADD>	18754 003	ORUDIS; KETOPROFEN	3641127	FEB 08, 1991		NCE	JAN 09, 1991
>ADD>	19010 001	LUPRON; LEUPROLIDE ACETATE	4005063	JAN 25, 1996		NCE	APR 09, 1990
>ADD>	16763 001	SULFAMYLON; MAFENIDE ACETATE	3497599	JAN 26, 1988	U-12		
>ADD>	17862 001	REGLAN; METOCLOPRAMIDE HYDROCHLORIDE	4536386	AUG 20, 2002	U-13		
>DLT>	18873 002	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1993		NCE	DEC 30, 1990
>ADD>	18873 002	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1995		NCE	DEC 30, 1990
>DLT>	18873 003	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1993		NCE	DEC 30, 1990
>ADD>	18873 003	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1995		NCE	DEC 30, 1990
>DLT>	18873 004	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1993		NCE	DEC 30, 1990
>ADD>	18873 004	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1995		NCE	DEC 30, 1990
>ADD>	18677 001	CESAMET; NABILONE	3920809	NOV 18, 1992		NCE	DEC 26, 1990
>ADD>			3928598	DEC 23, 1992	U-6		
>ADD>			4087545	MAY 02, 1995	U-7		
>ADD>			4087547	MAY 02, 1995	U-8		
>ADD>	17031 001	OVRETTE; NORGESTREL	3666858	MAY 30, 1989	U-2		
>ADD>			3666858	MAY 30, 1989	U-3		
>ADD>			3666858	MAY 30, 1989	U-1		
>DLT>	18859/001	VIRAZOLE; RIBAVIRIN	4211771	JUL 08, 1997		NCE	DEC/31/ 1990
>ADD>	18859 001	VIRAZOLE; RIBAVIRIN	4211771	JUL 08, 1999		NCE	DEC 31, 1990
>DLT>	18217 001	SUPROL; SUPROFEN	4035376	JUL 12, 1994		NCE	DEC 24, 1990
>ADD>	18217 001	SUPROL; SUPROFEN	4035376	JUL 12, 1996		NCE	DEC 24, 1990
>ADD>	18963 001	CHOLETEC; TECHNETIUM TC-99M MEBROFENIN KIT	4418208	NOV 29, 2000		NCE	JAN 21, 1992
>ADD>	14103 003	ONCOVIN; VINCRISTINE SULFATE	4619935	OCT 28, 2003			

SUBSCRIPTION FORM

APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 7TH EDITION (1987)

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DESCRIPTION	QUANTITY	UNIT PRICE	TOTAL PRICE
The 7th Edition is published in March 1987. Subscription includes the Approved Drug Products publication and monthly Cumulative Supplements. DOMESTIC (Stock No. 917-001-00000-6)		@ $86.00	$
FOREIGN (Stock No. 917-001-00000-6)		@ $107.50	$
ENTER TOTAL			$