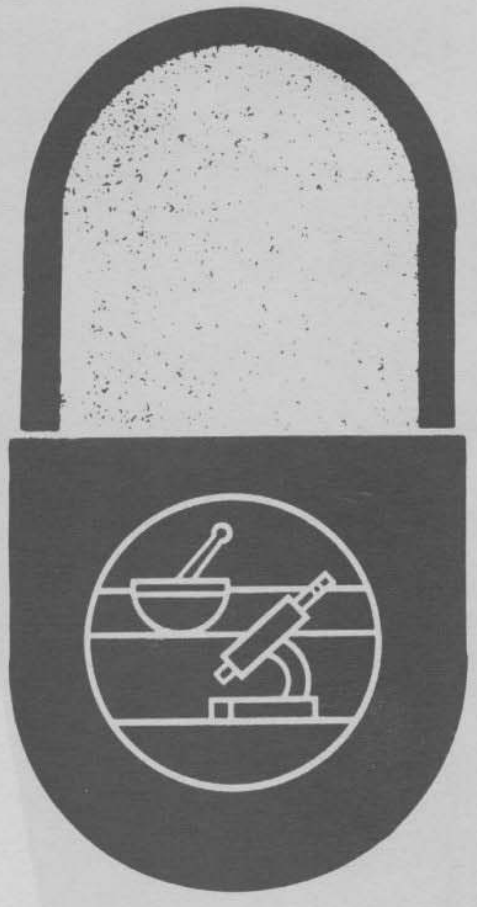
CUMULATIVE SUPPLEMENT 2

JAN'87-FEB'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

A recent approval has shown that the language in the "BC" code definition did not accurately reflect the use of the BC code for controlled-release products which may meet bioequivalence criteria for approval, but differ in rate such that they would not be considered therapeutically equivalent.

Therefore, please note that on pages 1-5 and 1-6 of the Introduction to the Approved Drug Products with Therapeutic Equivalence Evaluations, 7th Edition, the language defining the AB and BC codes has been revised.

AB

Products meeting necessary bioequivalence requirements

The AB evaluation generally denotes products that: (1) contain an active ingredient in a dosage form for which the submission of bioavailability or clinical data is required for approval or to permit therapeutic equivalence evaluations, and (2) for which the applicant has provided adequate studies to establish the bioavailability and bioequivalence of its product. Products generally will be coded AB if a study is submitted desmonstrating bioequivalence, even if the study currently is not required for approval. This category also includes those few drugs with more than one approved application but only one manufacturer. It should be noted that if only one product under a drug ingredient heading is coded AB, it signifies that only that product is supported by bioavailability data. It does not signify that this product is therapeutically equivalent to the other drugs under the same heading. Thus, one product under a drug ingredient heading, coded AB is not therapeutically equivalent to a drug product under the same heading that is coded BD, BP, or BT. Drugs coded AB under an ingredient heading are considered therapeutically equivalent only to other drugs coded AB under that heading.

BC

Controlled-release tablets, controlled-release capsules, and controlled-release injectables

Although bioavailability studies have been conducted on these dosage forms, they are subject to bioavailability differences, primarily because firms developing controlled-release products for the same active ingredient rarely employ the same formulation approach. FDA, therefore, does not evaluate different controlled-release dosage forms containing the same active ingredient in equal strength as therapeutically equivalent unless equivalence between individual products for both rate and extent has been specifically demonstrated through appropriate bioequivalence studies. Controlled-release products for which such bioequivalence data are available have been coded AB.

Please note the following printing errors to the Approved Drug Products List with Therapeutic Equivalence Evaluations, 7th Edition:

- The locator tab for the "OTC Drug Product List" is placed incorrectly within the List.
- There is no locator tab on the back cover for the "Discontinued Drug Product List."
- The bracketed products which appear below are corrections to a printing error that appeared on page 3-204. Please record the correct NDA Numbers in the List.

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

	PROCAINAMIDE HCL		
AB	DANBURY PHARMACAL	250MG	N83287 001
AB		375MG	N84403 001
AB		500MG	N84280 001
AB	LANNETT	250MG	N83693 001
AB		500MG	N84696 001
AB	LEDERLE LABS/AM CYAN	250MG	N86942 001
AB		375MG	[N86952 001
AB		500MG	N86943 001
AB	VANGARD LABS/MWM	250MG	N87643 001]
			JUN 01, 1982
AB		500MG	N87875 001
			JUN 01, 1982
AB	ZENITH LABORATORIES	250MG	N84604 001
AB		375MG	N84595 001
AB		500MG	N84606 001
	PROCAPAN		
AB	PANRAY/ORMONT DRUG	250MG	N83553 002
	PRONESTYL		
AB	ER SQUIBB AND SONS	250MG	N07335 001
AB		375MG	N07335 004
AB		500MG	N07335 003

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with

THERAPEUTIC EQUIVALENCE EVALUATIONS

7TH EDITION

CUMULATIVE SUPPLEMENT 2

FEBRUARY 1987

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7th EDITION

CUMULATIVE SUPPLEMENT 2

FEBRUARY 1987

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 List will then be added to the "Discontinued Drug Product 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 List 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.

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	NEW ABBREVIATED NAME
COOPERVISION PHARMS	IOLAB PHARMACEUTICALS	IOLAB

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 2

	JAN '87	FEB '87	CUMULATIVE
DRUG PRODUCTS ADDED:	83	75	158
NEWLY APPROVED	81	75	156
DESI EFFECTIVE	2	0	2
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	83	75	158
SINGLE SOURCE PRODUCTS APPROVED	12	7	19
MULTISOURCE DRUG PRODUCTS APPROVED	71	68	139
NEW MOLECULAR ENTITIES APPROVED:	1	0	1
AS THE ENTITY	1	0	1
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	0	0

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

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

AB	MIKART	325MG;50MG;40MG	N89175 001	JAN 21, 1987

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

> DLT >		/HYDROCODONE/			
> ADD >		TYCOLET			
	AB	MCNEIL PHARM	500MG;5MG	N89385 001	AUG 27, 1986

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

AB	PUREPAC	650MG;100MG	N70910 001	JAN 02, 1987
AB	SUPERPHARM	650MG;100MG	N71319 001	JAN 06, 1987

ACETOHEXAMIDE

TABLET; ORAL
ACETOHEXAMIDE

> ADD >	AB	BARR LABS	250MG	N70869 001	FEB 09, 1987
> ADD >					
> ADD >	AB		500MG	N70870 001	FEB 09, 1987
> ADD >					

ALBUTEROL SULFATE

SOLUTION; INHALATION
PROVENTIL

	SCHERING	EQ 0.083% BASE	N19243 002	JAN 14, 1987
AN		EQ 0.5% BASE	N19243 001	JAN 14, 1987

VENTOLIN

AN	GLAXO	EQ 0.5% BASE	N19269 002	JAN 16, 1987

ALLOPURINOL

TABLET; ORAL
ALLOPURINOL

AB	MUTUAL PHARM	100MG	N71449 001	JAN 09, 1987
AB		300MG	N71450 001	JAN 09, 1987

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HCL

	AB	BOLAR PHARM	100MG	N71382 001	JAN 21, 1987
> ADD >	AB	INVAMED	100MG	N71293 001	FEB 18, 1987
> ADD >					

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

> ADD >	AB	BARR LABS	150MG	N89423 001	FEB 17, 1987
> ADD >					
> DLT >	/AB/	/IKAPHARM/	/10MG/	/N86610 001/	
> DLT >	/AB/		/25MG/	/N86859 001/	
> DLT >	/AB/		/50MG/	/N86857 001/	
> DLT >	/AB/		/75MG/	/N86860 001/	
> DLT >	/AB/		/100MG/	/N86854 001/	
> DLT >	/AB/		/150MG/	/N86853 001/	
> ADD >	AB	LEMMON	10MG	N86610 001	
> ADD >	AB		25MG	N86859 001	
> ADD >	AB		50MG	N86857 001	
> ADD >	AB		75MG	N86860 001	
> ADD >	AB		100MG	N86854 001	
> ADD >	AB		150MG	N86853 001	

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM

	AP	INTL MEDTN SYS	EQ 1GM BASE/VIAL	N62634 002	JAN 09, 1987
	AP		EQ 2GM BASE/VIAL	N62634 003	JAN 09, 1987

POLYCILLIN-N

> ADD >	AP	BRISTOL LABS	EQ 1GM BASE/VIAL	N62738 001	FEB 19, 1987
> ADD >					
> ADD >	AP		EQ 2GM BASE/VIAL	N62738 002	FEB 19, 1987
> ADD >					

ATROPINE

INJECTABLE; INJECTION

ATROPEN

AP	SURVIVAL TECH	EQ 2MG SULFATE/0.7ML	N17106 001	

ATROPINE

AP	KALI DUPHAR	EQ 2MG SULFATE/0.7ML¤	N71295 001	JAN 30, 1987

BETAMETHASONE

CREAM; TOPICAL

CELESTONE

>ADD>	@ SCHERING	0.2%	N14762 001	

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

>ADD> AB	NMC LABS	EQ 0.05% BASE¤	N70885 001	
>ADD>			FEB 03, 1987	

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

>ADD> AB	NMC LABS	EQ 0.05% BASE¤	N71085 001	
>ADD>			FEB 03, 1987	

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE

>ADD> AB	NMC LABS	EQ 0.05% BASE¤	N71012 001	
>ADD>			FEB 03, 1987	

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

>ADD>	LYPHOMED	100MG/ML¤	N71298 001	
>ADD>			FEB 13, 1987	

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPIVACAINE HCL

>ADD> AP	ABBOTT LABS	0.25%¤	N70590 001	
>ADD>			FEB 17, 1987	
>ADD> AP		0.25%¤	N70583 001	
>ADD>			FEB 17, 1987	
>ADD> AP		0.5%¤	N70584 001	
>ADD>			FEB 17, 1987	

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

AB	PARKE DAVIS	200MG¤	N70429 001	JAN 02, 1987

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CLAFORAN

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

CEFOXITIN SODIUM

INJECTABLE; INJECTION

MEFOXIN

	MSD	EQ 1GM BASE/VIAL¤	N62757 001	JAN 08, 1987
		EQ 2GM BASE/VIAL¤	N62757 002	JAN 08, 1987

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

>ADD>	ROCHE	EQ 10MG BASE/ML¤	N50624 001	FEB 11, 1987
>ADD>		EQ 20MG BASE/ML¤	N50624 002	FEB 11, 1987
>ADD>		EQ 40MG BASE/ML¤	N50624 003	FEB 11, 1987

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

>ADD> AB	BIOCRAFT LABS	EQ 250MG BASE¤	N62702 001	FEB 13, 1987
>ADD> AB		EQ 500MG BASE¤	N62702 002	FEB 13, 1987

CEPHALEXIN MONOHYDRATE

AB	VITARINE	EQ 250MG BASE¤	N62159 001	
AB		EQ 500MG BASE¤	N62159 002	

KEFLEX

AB	LILLY	EQ 250MG BASE	N50405 002	
AB		EQ 250MG BASE	N62118 001	
AB		EQ 500MG BASE	N50405 003	
AB		EQ 500MG BASE	N62118 002	

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

> ADD >		CEPHALEXIN			
> ADD >	AB	BIOCRAFT LABS	EQ 125MG BASE/5ML¤	N62703 001	
> ADD >				FEB 13, 1987	
> ADD >	AB		EQ 250MG BASE/5ML¤	N62703 002	
> ADD >				FEB 13, 1987	
		KEFLEX			
> ADD >	AB	LILLY	EQ 125MG BASE/5ML	N50406 001	
> ADD >	AB		EQ 125MG BASE/5ML	N62117 002	
> ADD >	AB		EQ 250MG BASE/5ML	N50406 002	
> ADD >	AB		EQ 250MG BASE/5ML	N62117 003	

TABLET; ORAL

> ADD >		KEFLET			
> ADD >		LILLY	EQ 250MG BASE¤	N50440 003	
> ADD >				FEB 26, 1987	
> ADD >			EQ 500MG BASE	N50440 001	
> ADD >			EQ 1GM BASE	N50440 002	
> DLT >		/KEFLEX/			
> DLT >		/LILLY/	/EQ 1GM BASE/	/N50440 002/	

CEPHRADINE

CAPSULE; ORAL

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

POWDER FOR RECONSTITUTION; ORAL

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

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION

		CHLOR-TRIMETON			
> ADD >	AP	③ SCHERING	100MG/ML	N08794 001	

CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE

TABLET; ORAL

> ADD >		CLONIDINE HCL AND CHLORTHALIDONE			
> ADD >	AB	MYLAN PHARMS	15MG;0.1MG¤	N71323 001	
> ADD >				FEB 09, 1987	
> ADD >	AB		15MG;0.2MG¤	N71324 001	
> ADD >				FEB 09, 1987	
> ADD >	AB		15MG;0.3MG¤	N71325 001	
> ADD >				FEB 09, 1987	

CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE

TABLET; ORAL

		COMBIPRES			
> ADD >	AB	BOEHR INGEL	15MG;0.1MG	N17503 001	
> ADD >	AB		15MG;0.2MG	N17503 002	
> ADD >	AB		15MG;0.3MG	N17503 003	
				APR 10, 1984	

CILASTATIN SODIUM; IMIPENEM

INJECTABLE; INJECTION

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

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL

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

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

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

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

		CYCLOGYL			
> ADD >	AT	ALCON LABS	0.5%	N84109 001	
		PENTOLAIR			
> ADD >	AT	PHARMAFAIR	0.5%	N88643 001	
> ADD >				FEB 09, 1987	

DIAZEPAM

TABLET; ORAL
DIAZEPAM

> ADD >	AB	DANBURY PHARMA	2MG¤	N71134 001	
> ADD >				FEB 03, 1987	
> ADD >	AB		5MG¤	N71135 001	
> ADD >				FEB 03, 1987	
> ADD >	AB		10MG¤	N71136 001	
> ADD >				FEB 03, 1987	

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

AA	MUTUAL PHARM	25MG¤	N89488 001	
			JAN 02, 1987	
AA		50MG¤	N89489 001	
			JAN 02, 1987	

DIPYRIDAMOLE

TABLET; ORAL
PERSANTINE

> ADD >	BOEHR INGEL	50MG¤	N12836 004	
> ADD >			FEB 06, 1987	
> ADD >		75MG¤	N12836 005	
> ADD >			FEB 06, 1987	

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE

AB	INTERPHARM	EQ 100MG BASE¤	N71190 001	
			JAN 15, 1987	
AB		EQ 150MG BASE¤	N71191 001	
			JAN 15, 1987	
> ADD > AB	SUPERPHARM	EQ 100MG BASE¤	N70940 001	
> ADD >			FEB 09, 1987	
> ADD > AB		EQ 150MG BASE¤	N70941 001	
> ADD >			FEB 09, 1987	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL

> ADD > AP	LUITPOLD PHARMS	40MG/ML¤	N70799 001	
> ADD >			FEB 11, 1987	
> ADD > AP		80MG/ML¤	N70820 001	
> ADD >			FEB 11, 1987	
> ADD > AP		160MG/ML¤	N70826 001	
> ADD >			FEB 11, 1987	

ESTRADIOL CYPIONATE

INJECTABLE; INJECTION
ESTRADIOL CYPIONATE

> ADD > AO	QUAD PHARMS	5MG/ML¤	N89310 001	
> ADD >			FEB 09, 1987	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
GYNEX 0,5/35E-21

AB	GYNEX LABS	0.035MG;0.5MG¤	N70684 001	
			JAN 29, 1987	

GYNEX 1/35E-21

AB	GYNEX LABS	0.035MG;1MG¤	N70685 001	
			JAN 29, 1987	

TABLET; ORAL-28
GYNEX 0,5/35E-28

AB	GYNEX LABS	0.035MG;0.5MG¤	N70686 001	
			JAN 29, 1987	

GYNEX 1/35E-28

AB	GYNEX LABS	0.035MG;1MG¤	N70687 001	
			JAN 29, 1987	

FAMOTIDINE

POWDER FOR RECONSTITUTION; ORAL
PEPCID

> ADD >	MS&D RES LABS	40MG/5ML¤	N19527 001	
> ADD >			FEB 02, 1987	

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

AP	LYPHOMED	50MG/ML¤	N89428 001	
			JAN 12, 1987	
> ADD > AP	QUAD PHARMS	50MG/ML¤	N89368 001	
> ADD >			FEB 03, 1987	
> ADD > AP		50MG/ML¤	N89455 001	
> ADD >			FEB 03, 1987	

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

AP	CARTER GLOGAU	10MG/ML¤	N70604 001	
			JAN 02, 1987	

TABLET; ORAL
FUROSEMIDE

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

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

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

HALOPERIDOL

TABLET; ORAL

		HALOPERIDOL			
AB	BARR LABS	0.5MG¤	N71156 001 JAN 02, 1987		
AB		1MG¤	N71157 001 JAN 02, 1987		
AB		2MG¤	N71172 001 JAN 02, 1987		
>ADD> AB	QUANTUM PHARMCS	0.5MG¤	N71255 001 FEB 17, 1987		
>ADD> AB		1MG¤	N71269 001 FEB 17, 1987		
>ADD> AB		2MG¤	N71256 001 FEB 17, 1987		
>ADD> AB		5MG¤	N71257 001 FEB 17, 1987		
>ADD> AB	ROXANE LABS	0.5MG¤	N71128 001 FEB 17, 1987		
>ADD> AB		1MG¤	N71129 001 FEB 17, 1987		
>ADD> AB		2MG¤	N71130 001 FEB 17, 1987		
>ADD> AB		5MG¤	N71131 001 FEB 17, 1987		

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

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

HEXACHLOROPHENE

EMULSION; TOPICAL

		SOY-DOME			
>ADD> AT	∂ MILES PHARMS	3%	N17405 001		

HYDRALAZINE HYDRCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

		HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE			
>ADD> AB	SUPERPHARM	25MG;25MG¤	N89200 001 FEB 09, 1987		
>ADD> AB		50MG;50MG¤	N89201 001 FEB 09, 1987		

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

		METHYLDOPA AND HYDROCHLOROTHIAZIDE			
>ADD> AB	PAR PHARM	15MG;250MG¤	N70616 001 FEB 02, 1987		
>ADD> AB		25MG;250MG¤	N70612 001 FEB 02, 1987		
>ADD> AB		30MG;500MG¤	N70613 001 FEB 02, 1987		
>ADD> AB		50MG;500MG¤	N70614 001 FEB 02, 1987		

HYDROCORTISONE

OINTMENT; TOPICAL

		HYDROCORTISONE			
>ADD> AT	PHARMADERM	1%¤	N88842 001 FEB 09, 1987		

HYDROCORTISONE BUTYRATE

LOTION; TOPICAL

		LOCOID			
>ADD>	GIST BROCADES	0.1%¤	N19116 001 FEB 25, 1987		

HYDROXPROGESTERONE CAPROATE

INJECTABLE; INJECTION

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

HYDROXYSTILBAMIDINE ISETHIONATE

INJECTABLE; INJECTION
HYDROXYSTILBAMIDINE ISETHIONATE

>ADD>		∂ MERRELL DOW	225MG/AMP	N09166 001	

HYDROXYZINE PAMOATE

CAPSULE; ORAL
HYDROXYZINE PAMOATE

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

IBUPROFEN

TABLET; ORAL
IBUPROFEN

>ADD>	AB	BARR LABS	800MG¤	N71448 001 FEB 18, 1987
>ADD>				

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

>ADD>	AB	MUTUAL PHARM	25MG¤	N70899 001 FEB 09, 1987
>ADD>				
>ADD>	AB		50MG¤	N70900 001 FEB 09, 1987
>ADD>				

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

>ADD>	AB	BARR LABS	5MG	N86166 002 SEP 19, 1986
>ADD>	AB		10MG¤	N86169 001 SEP 19, 1986
>ADD>	AB		20MG¤	N86167 001 SEP 19, 1986
>ADD>	AB	SUPERPHARM	5MG¤	N89190 001 FEB 17, 1987
>ADD>	AB		10MG¤	N89191 001 FEB 17, 1987
>ADD>	AB		20MG¤	N89192 001 FEB 17, 1987
>ADD>				

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

	AP	ELKINS SINN	EQ 50MG BASE/VIAL¤	N70480 001 JAN 02, 1987

POWDER FOR RECONSTITUTION; ORAL
LEUCOVORIN CALCIUM

		LEDERLE LABS	EQ 60MG BASE/VIAL¤	N08107 003 JAN 30, 1987

LORAZEPAM

TABLET; ORAL
LORAZEPAM

>ADD>	AB	SUPERPHARM	0.5MG¤	N71245 001 FEB 09, 1987
>ADD>	AB		1MG¤	N71246 001 FEB 09, 1987
>ADD>	AB		2MG¤	N71247 001 FEB 09, 1987
>ADD>				

MANNITOL

INJECTABLE; INJECTION
MANNITOL 5% IN PLASTIC CONTAINER

	AP	ABBOTT LABS	5GM/100ML¤	N19603 001 JAN 08, 1987

MANNITOL 10% IN PLASTIC CONTAINER

	AP	ABBOTT LABS	10GM/100ML¤	N19603 002 JAN 08, 1987

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
ANTIVERT

		ROERIG	50MG	N10721 001 JAN 20, 1982

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM

>ADD>	AB	AM THERPTCS	EQ 50MG BASE¤	N71362 001 FEB 10, 1987
>ADD>	AB		EQ 100MG BASE¤	N71363 001 FEB 10, 1987
>ADD>				

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

> ADD >	AA	AM THERPTCS	500MG¤	N89417 001	FEB 11, 1987
> ADD >	AA		750MG¤	N89418 001	FEB 11, 1987

METHYLDOPA

TABLET; ORAL
METHYLDOPA

AB	PAR PHARM	125MG¤	N70535 001	JAN 02, 1987
AB		250MG¤	N70536 001	JAN 02, 1987
AB		500MG¤	N70537 001	JAN 02, 1987

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION
METHYLDOPATE HCL

AP	SOLOPAK LABS	50MG/ML¤	N70841 001	JAN 02, 1987

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

> ADD >	AB	BARR LABS	EQ 10MG BASE¤	N70660 001	FEB 10, 1987
> ADD >	AB	INVAMED	EQ 10MG BASE¤	N70850 001	FEB 03, 1987
> ADD >	AB	MARTEC PHARMS	EQ 10MG BASE¤	N70598 001	FEB 02, 1987

METRIZAMIDE

INJECTABLE; INJECTION
AMIPAQUE

> ADD >	WINTHROP BREON	2.5GM/VIAL	N17982 003	SEP 12, 1983

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION
MEZLIN

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

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL

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

NITROGLYCERIN

INJECTABLE; INJECTION
NITROSTAT

AP	PARKE DAVIS	5MG/ML¤	N70863 001	JAN 08, 1987
		10MG/ML¤	N70871 001	JAN 08, 1987
		10MG/ML¤	N70872 001	JAN 08, 1987

OXAZEPAM

TABLET; ORAL
OXAZEPAM

AB	BARR LABORATORIES	15MG¤	N70683 001	JAN 16, 1987
> ADD > AB	PARKE DAVIS	15MG¤	N71508 001	FEB 02, 1987

SERAX

AB	WYETH	15MG	N15539 008

POTASSIUM CHLORIDE

CAPSULE, CONTROLLED RELEASE; ORAL
MICRO-K 10

> ADD > BC	ROBINS	10MEQ	N18238 002	MAY 14, 1984

POTASSIUM CHLORIDE

> ADD > BC	KV PHARM	10MEQ¤	N70980 001	FEB 17, 1987

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

AP	CARTER GLOGAU	2MEQ/ML¤	N89421 001	JAN 02, 1987

PROCAINAMIDE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL
PROCAINAMIDE HCL

AB	BOLAR PHARM	1GM¤	N89520 001	JAN 15, 1987
AB	CORD LABS	500MG¤	N89370 001	JAN 09, 1987

PROCAN SR

AB	PARKE DAVIS	1GM	N88489 001	JAN 16, 1985

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCHLORPERAZINE MALEATE

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

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

AB	CHELSEA LABS	60MG¤	N70143 001	JAN 15, 1987

QUAZEPAM

TABLET; ORAL
DORMALIN

>ADD>	SCHERING	7.5MG¤	N18708 003	FEB 26, 1987

QUINDINE GLUCONATE

TABLET, CONTROLLED RELEASE; ORAL
QUINDINE GLUCONATE

>ADD>					
>ADD>	AB	MUTUAL PHARM	324MG¤	N89338 001	FEB 11, 1987
>ADD>					

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
SULFAMETHOXAZOLE AND TRIMETHOPRIM

AP	LYPHOMED	80MG/ML;16MG/ML¤	N70223 001	DEC 29, 1987 : JAN 16, 1987

SULFANILAMIDE

CREAM; VAGINAL
AVC

AT	MERRELL DOW	15%¤	N06530 003	JAN 27, 1987

VAGITROL

AT	LEMMON	15%	N88718 001	SEP 19, 1985

SUPPOSITORY; VAGINAL
AVC

	MERRELL DOW	1.05GM¤	N06530 004	JAN 27, 1987

SULFOXONE SODIUM

TABLET, ENTERIC COATED; ORAL
DIASONE SODIUM

>ADD>	∂ ABBOTT LABS	165MG	N06044 003	

TECHNETIUM TC-99M, MEBROFENIN KIT

INJECTABLE; INJECTION
CHOLETEC

	SQUIBB DIAGS	N/A¤	N18963 001	JAN 21, 1987

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
VERAPAMIL HCL

>ADD>	AP	WINTHROP BREON	2.5MG/ML¤	N70577 001	FEB 02, 1987
>ADD>					

VINCRISTINE SULFATE

INJECTABLE; INJECTION
VINCRISTINE SULFATE

>ADD>	AP	INTL PHARM	1MG/ML¤	N70873 001	FEB 19, 1987
>ADD>					

WARFARIN POTASSIUM

TABLET; ORAL

		ATHROMBIN-K		
>_ADD_>		@ PURDUE FRDRK	2MG	N11771 007
>_ADD_>		@	10MG	N11771 005
>_ADD_>		@	25MG	N11771 006

WARFARIN SODIUM

TABLET; ORAL

		ATHROMBIN		
>_ADD_>	BX	@ PURDUE FRDRK	5MG	N11771 003
>_ADD_>	BX	@	10MG	N11771 002
>_ADD_>		@	25MG	N11771 001

>ADD> ASPIRIN

>ADD> TABLET, CONTROLLED RELEASE; ORAL
>ADD> 8-HOUR BAYER
>ADD> WINTHROP BREON 650MG N16030 001
>ADD> MEASURIN
>ADD> WINTHROP BREON 650MG N16030 002

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL
BROMPHERIL
COPLEY PHARM 6MG;120MG¤ N89116 001
JAN 22, 1987

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
VICKS FORMULA 44
VICKS HLTH CARE 12.5MG/5ML¤ N70524 001
JAN 14, 1987

IBUPROFEN

TABLET; ORAL
IBUPROFEN
>ADD> INTERPHARM 200MG¤ N71333 001
>ADD> FEB 17, 1987
>ADD> PUREPAC 200MG¤ N71664 001
>ADD> FEB 03, 1987
NEUVIL
LUCHEM PHARMS 200MG¤ N71144 001
JAN 20, 1987
>ADD> TRENDAR
>ADD> WHITEHALL LABS 200MG N18989 002
>ADD> JUL 10, 1986

POVIDONE-IODINE

SPONGE; TOPICAL
E-Z SCRUB 241
DESERET 10%¤ N19476 001
JAN 07, 1987

NO FEBRUARY 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.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 7TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

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 FEBRUARY 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.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 7TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NAME OF DRUG	DATE	REVISED DATE
CLORAZEPATE DIPOTASSIUM	MAR 10, 1986	FEB 17, 1987
DISSOLUTION TESTING (GENERAL)	APR 01, 1978*	

* THIS DATE WAS INCORRECTLY LISTED IN THE 7TH EDITION AS APR 19, 1985.

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.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 7TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

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 09, 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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
LEUCOVORIN CALCIUM TABLET; ORAL	EQ 10MG BASE	86 P-0258/CP	LEDERLE LABS/AM CYAN	NEW STRENGTH	APPROVED JAN 16, 1987
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	0.5MG/ML (100 ML/CONTAINER)	86 P-0099/ CP0004	ABBOTT LABORATORIES	NEW STRENGTH	APPROVED FEB 02, 1987

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; DIHYDROCODEINE BITARTRATE CAPSULE; ORAL	356.4MG 20MG	86 P-0040/CP	DUNHALL PHARMACEUTICALS	NEW STRENGTH NEW COMBINATION	DENIED FEB 12, 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

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

EXCLUSIVITY TERMS

PATENT USE CODE

U-1	PREVENTION OF PREGNANCY
U-2	CYCLIC CONTROL
U-3	TREATMENT OF AMENORRHEA, DYSMENORRHEA, AND FUNCTIONAL UTERINE BLEEDING
U-4	TREATMENT OR PROPHYLAXIS OF ANGINA PECTORIS AND ARRHYTHMIA
U-5	TREATMENT OF HYPERTENSION
U-6	TREATING MAMMALS SUFFERING [FROM] ANXIETY
U-7	PROVIDING PREVENTION AND TREATMENT OF EMESIS AND NAUSEA IN MAMMALS
U-8	REDUCING INTRAVASCULAR PRESSURE IN MAMMALS
U-9	METHOD OF PRODUCING BRONCHODILATION
U-10	METHOD OF PRODUCING SYMPATHOMIMETIC EFFECTS
U-11	INCREASING CARDIAC CONTRACTILITY
U-12	TREATMENT OF BURNS
U-13	CONTROL OF EMESIS ASSOCIATED WITH ANY CANCER CHEMOTHERAPY AGENT
U-14	TREATMENT OF STRESS-INDUCED DEPRESSION
U-15	DIAGNOSTIC METHOD FOR DISTINGUISHING BETWEEN HYPOTHALMIC MALFUNCTIONS OR LESIONS IN HUMANS
U-16	TREATMENT OR PROPHYLAXIS OF CARDIAC DISORDERS

	APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	18917 001	SECTRAL; ACEBUTOLOL HYDROCHLORIDE	3857952	DEC 31, 1993	U-4		
	18917 003	SECTRAL; ACEBUTOLOL HYDROCHLORIDE	3857952	DEC 31, 1993	U-4		
	19243 001	PROVENTIL; ALBUTEROL SULFATE	3705233	DEC 05, 1989			
			3644353	FEB 22, 1989		NDF	JAN 14, 1990
	19243 002	PROVENTIL; ALBUTEROL SULFATE	3705233	DEC 05, 1989			
			3644353	FEB 22, 1989		NDF	JAN 14, 1990
	19353 001	ALFENTA; ALFENTANIL HYDROCHLORIDE	4167574	SEP 11, 1996		NCE	DEC 29, 1991
	18700 001	INOCOR; AMRINONE LACTATE	4072746	FEB 07, 1995	U-11	NCE	JUL 31, 1994
	19270 001	BETOPTIC; BETAXOLOL HYDROCHLORIDE	4252984	JUL 31, 1999		NCE	AUG 30, 1990
	18770 001	TORNALATE; BITOLTEROL MESYLATE	4336400	JUN 22, 1999	U-10		
			4336400	JUN 22, 1999	U-9		
			4336400	JUN 22, 1999	U-10		
	18644 001	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1994			
	18644 002	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1994			
	18644 003	WELLBUTRIN; BUPROPION HYDROCHLORIDE	3885046	MAY 20, 1994			
	19215 001	FEMSTAT; BUTOCONAZOLE NITRATE	4078071	MAR 07, 1997		NCE	NOV 25, 1990
>DLT>	*18470 001*	*CIBACALCIN; CALCITONIN, HUMAN*	*RE32742*	*JUN 30, 1998*		*NCE*	*OCT 31, 1991*
>ADD>	18470 001	CIBACALCIN; CALCITONIN, HUMAN	RE32347	JUN 30, 1998		NCE	OCT 31, 1991
						ODE	OCT 31, 1993
	19322 001	TEMOVATE; CLOBETASOL PROPIONATE	3721687	MAR 20, 1992		NCE	DEC 27, 1990
	19323 001	TEMOVATE; CLOBETASOL PROPIONATE	3721687	MAR 20, 1992		NCE	DEC 27, 1990
>ADD>	12836 004	PERSANTINE; DIPYRIDAMOLE				I-49	DEC 22, 1989
>ADD>	12836 005	PERSANTINE; DIPYRIDAMOLE				I-49	DEC 22, 1989
	17820 002	DOBUTREX; DOBUTAMINE HYDROCHLORIDE	3987200	OCT 19, 1993	U-11		
>ADD>	19386 002	BREVIBLOC; ESMOLOL HYDROCHLORIDE	4593119	JUN 03, 2003		NCE	DEC 31, 1991
>ADD>			4387103	JUN 07, 2000	U-16		
	16672 001	OVRAL; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
	16806 001	OVRAL-28; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
	17612 001	LO/OVRAL; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
	17802 001	LO/OVRAL-28; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
	18668 001	NORDETTE-21; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
	18782 001	NORDETTE-28; ETHINYL ESTRADIOL	3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		

	APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19190 001	TRIPHASIL-28; ETHINYL ESTRADIOL	3957982	MAY 18, 1993	U-1		
			3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
	19192 001	TRIPHASIL-21; ETHINYL ESTRADIOL	3957982	MAY 18, 1993	U-1		
			3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
>ADD>	19527 001	PEPCID; FAMOTIDINE	4283408	AUG 11, 1998		NCE	OCT 15, 1991
	18830 001	TAMBOCOR; FLECAINIDE ACETATE	4005209	JAN 25, 1996			
	18830 002	TAMBOCOR; FLECAINIDE ACETATE	4005209	JAN 25, 1996			
	19404 001	OCUFEN; FLURBIPROFEN SODIUM	3793457	FEB 19, 1991			
	18123 001	FACTREL; GONADORELIN HYDROCHLORIDE	3755427	AUG 28, 1990		NCE	DEC 31, 1991
			4110438	AUG 29, 1995	U-14		
			3947569	MAR 30, 1993	U-15		
	18123 002	FACTREL; GONADORELIN HYDROCHLORIDE	4110438	AUG 29, 1995	U-14		
			3947569	MAR 30, 1993	U-15		
	18123 003	FACTREL; GONADORELIN HYDROCHLORIDE	4110438	AUG 29, 1995	U-14		
			3947569	MAR 30, 1993	U-15		
	18587 001	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5		
	18587 002	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5		
	18587 003	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5		
	18956 001	OMNIPAQUE 180; IOHEXOL	4250113	DEC 26, 1999		NCE	DEC 26, 1990
	18956 002	OMNIPAQUE 240; IOHEXOL	4250113	DEC 26, 1999		NCE	DEC 26, 1990
	18956 003	OMNIPAQUE 300; IOHEXOL	4250113	DEC 26, 1999		NCE	DEC 26, 1990
	18956 004	OMNIPAQUE 350; IOHEXOL	4250113	DEC 26, 1999		NCE	DEC 26, 1990
	18735 001	ISOVUE-M 200; IOPAMIDOL	4001323	JAN 04, 1996		NCE	DEC 31, 1990
	18735 002	ISOVUE-300; IOPAMIDOL	4001323	JAN 04, 1996		NCE	DEC 31, 1990
	18735 003	ISOVUE-370; IOPAMIDOL	4001323	JAN 04, 1996		NCE	DEC 31, 1990
	18735 004	ISOVUE-M 300; IOPAMIDOL	4001323	JAN 04, 1996		NCE	DEC 31, 1990
	13295 002	CONRAY-43; IOTHALAMATE MEGLUMINE				I-54	DEC 18, 1989
	18905 002	HEXABRIX; IOXAGLATE MEGLUMINE	4094966	JUN 13, 1995		I-54	OCT 22, 1989
			4065554	DEC 27, 1994		I-36	OCT 22, 1989
			4065553	DEC 27, 1994		I-6	OCT 22, 1989
			4014986	MAR 29, 1996		NCE	JUL 26, 1990
						I-55	OCT 22, 1989
						I-56	OCT 22, 1989
						I-57	OCT 22, 1989
						I-58	OCT 22, 1989
						I-59	OCT 22, 1989
						I-60	OCT 22, 1989
						I-61	OCT 22, 1989

	APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	18754 002	ORUDIS; KETOPROFEN	3641127	FEB 08, 1991		NCE	JAN 09, 1991
	18754 003	ORUDIS; KETOPROFEN	3641127	FEB 08, 1991		NCE	JAN 09, 1991
	19010 001	LUPRON; LEUPROLIDE ACETATE	4005063	JAN 25, 1996		NCE	APR 09, 1990
	16763 001	SULFAMYLON; MAFENIDE ACETATE	3497599	JAN 26, 1988	U-12		
	17862 001	REGLAN; METOCLOPRAMIDE HYDROCHLORIDE	4536386	AUG 20, 2002	U-13		
	18873 002	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1995		NCE	DEC 30, 1990
	18873 003	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1995		NCE	DEC 30, 1990
	18873 004	MEXITIL; MEXILETINE HYDROCHLORIDE	3954872	MAY 04, 1995		NCE	DEC 30, 1990
	18677 001	CESAMET; NABILONE	4087547	MAY 02, 1995	U-8		
			4087545	MAY 02, 1995	U-7		
			3928598	DEC 23, 1992	U-6		
			3920809	NOV 18, 1992		NCE	DEC 26, 1990
>ADD>	19384 002	NOROXIN; NORFLOXACIN	4639458	JAN 27, 2004			
	17031 001	OVRETTE; NORGESTREL	3666858	MAY 30, 1989	U-1		
			3666858		U-2		
			3666858		U-3		
>ADD>	18708 003	DORMALIN; QUAZEPAM	3920818	NOV 18, 1992			
>ADD>			3845039	OCT 29, 1991		NCE	DEC 27, 1990
	18859 001	VIRAZOLE; RIBAVIRIN	4211771	JUL 08, 1999		NCE	DEC 31, 1990
>DLT>	19518 001	KB/1800R; SODIUM MONOFLUOROPHOSPHATE				MS	AUG 06, 1989
>ADD>	19518 002	EXTRA-STRENGTH AIM; SODIUM MONOFLUOROPHOSPHATE				NS	AUG 06, 1989
	18217 001	SUPROL; SUPROFEN	4035376	JUL 12, 1996		NCE	DEC 24, 1990
	18963 001	CHOLETEC; TECHNETIUM TC-99M MEBROFENIN KIT	4418208	NOV 29, 2000		NCE	JAN 21, 1992
>DLT>	19415 001	METRODIN; UROFOLLITROPIN				ME	SEP 18, 1989
>ADD>	19415 002	METRODIN; UROFOLLITROPIN				NE	SEP 18, 1989
	14103 003	ONCOVIN; VINCRISTINE SULFATE	4619935	OCT 28, 2003			

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