CUMULATIVE
SUPPLEMENT 3
JAN'87-MAR'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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7TH EDITION

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MARCH 1987

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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 Prescription Drug Product List, OTC Drug Product List and the Patent and Exclusivity Data 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 Prescription Drug Product List, OTC Drug Product List and the Patent and Exclusivity Data 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 the Prescription and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data will be dropped in subsequent Cumulative Supplements.**

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 "∂" symbol to designate their non-marketed status. All products having a "∂" 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 Hydrochloride Triprolidine Hydrochloride Tablet or Capsule; Oral	60mg 2.5mg
Pseudoephedrine Hydrochloride Triprolidine Hydrochloride Syrup; Oral	30mg/5ml 1.25mg/5ml
Triprolidine Hydrochloride Syrup; Oral	1.25mg/5ml
Triprolidine Hydrochloride 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

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	NEW ABBREVIATED NAME
CARTER-GLOGAU LABORATORIES	STERIS LABORATORIES	STERIS LABS
ASCOT HOSPITAL PHARMACEUTICALS	ASCOT DIVISION OF TRAVENOL LABORATORIES	ASCOT

1.7 CONJUGATED ESTROGEN TABLETS

Conjugated estrogen tablets are presently coded BS (not therapeutically equivalent) based on *in vivo* data indicating differences produced by different conjugated estrogen tablets in urinary excretion levels of the active ingredients. These differences were believed to be directly related to the differences in composition permitted by the official standards for the estrogenic steroids in conjugated estrogen products. The USP monograph was recently revised to narrow the range of differences permitted.

Nevertheless, FDA's Biopharmaceutics Research Branch recently demonstrated problems with dissolution of conjugated estrogen tablets, apparently because of the products' coating. The coating on at least some conjugated estrogen products behaves like an enteric coating. Therefore, the Agency has decided to require *in vivo* bioequivalence studies for all new applications for conjugated estrogen tablets and for any such product to be coded AB (therapeutically equivalent). Thus, all new or pending applications for conjugated estrogen tablets must contain *in vivo* studies and previously approved conjugated estrogen tablets will be coded as BP (not therapeutically equivalent) unless an acceptable *in vivo* bioequivalence study is submitted by the applicant holder. Requests for guidance on conducting bioavailability/bioequivalence studies should be addressed to the Division of Bioequivalence, HFN-250, 5600 Fishers Lane, Rockville, MD 20857.

1.8 CORRECTIONS TO THE 7TH EDITION

a. The locator tab for the "OTC Drug Product List" is placed incorrectly within the List.

b. There is no locator tab on the back cover for the "Discontinued Drug Product List."

c. 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 demonstrating 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.

d. In the following products dextrose and sodium chloride are considered vehicles and not active ingredients, therefore, they will no longer appear as part of the active ingredient heading. These ingredients may continue to appear in the trade name for those products which contain them. The active ingredient headings in the 7th Edition affected are:

Alcohol; Dextrose
Aminophylline; Sodium Chloride
Ammonium Chloride; Sodium Chloride
Bretylium Tosylate; Dextrose
Cefazolin Sodium; Dextrose
Cefoperazone Sodium; Dextrose
Cefotaxime Sodium; Dextrose
Cefotaxime Sodium; Sodium Chloride
Cefoxitin Sodium; Dextrose
Cefoxitin Sodium; Sodium Chloride
Ceftizoxime Sodium; Dextrose
Cephalothin Sodium; Dextrose
Cephalothin Sodium; Sodium Chloride
Cimetidine Hydrochloride; Sodium Chloride
Dextrose; Dopamine Hydrochloride
Dextrose; Gentamicin Sulfate
Dextrose; Lidocaine Hydrochloride
Dextrose; Heparin Sodium
Dextrose; Mannitol
Dextrose; Oxytocin
Dextrose; Theophylline
Gentamicin Sulfate; Sodium Chloride
Heparin Sodium; Sodium Chloride
Ranitidine Hydrochloride; Sodium Chloride

e. The following products 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
LEDERLE LABS/AM CYAN

	375MG	N86952 001
	500MG	N86943 001
VANGARD LABS/MWM	250MG	N87643 001

1.9 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 3

	JAN '87	FEB '87	MAR '87	CUMULATIVE
DRUG PRODUCTS ADDED:	83	75	94	252
NEWLY APPROVED	81	75	94	250
DESI EFFECTIVE	2	0	0	2
REMARKETED	0	0	0	0
DRUG PRODUCTS REMOVED:	0	0	0	0
WITHDRAWN APPROVAL	0	0	0	0
RX TO OTC SWITCH	0	0	0	0
NET GAIN IN DRUG PRODUCTS	83	75	94	252
SINGLE SOURCE PRODUCTS APPROVED	12	7	6	25
MULTISOURCE DRUG PRODUCTS APPROVED	71	68	88	227
NEW MOLECULAR ENTITIES APPROVED:	1	0	1	2
AS THE ENTITY	1	0	1	2
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	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 INTRODUCTION, PAGE I-8 OF THE LIST)

PRESCRIPTION DRUG PRODUCT LIST
7TH EDITION
CUMULATIVE SUPPLEMENT NUMBER 3 / JAN'87 - MAR 87

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

> ADD >		**ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 2**	
> ADD >	AA	AM THERPTCS 300MG;15MG¤	N89478 001 MAR 03, 1987
> ADD >			
> ADD >	AA	300MG;15MG¤	N89481 001 MAR 03, 1987
> ADD >			
> ADD >		**ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 3**	
> ADD >	AA	AM THERPTCS 300MG;30MG¤	N89479 001 MAR 03, 1987
> ADD >			
> ADD >	AA	300MG;30MG¤	N89482 001 MAR 03, 1987
> ADD >			
> ADD >		**ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 4**	
> ADD >	AA	AM THERPTCS 300MG;60MG¤	N89480 001 MAR 03, 1987
> ADD >			
> ADD >	AA	300MG;60MG¤	N89483 001 MAR 03, 1987
> ADD >			

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
/~~TYCODONE~~/
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

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

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
AB	INVAMED	100MG¤	N71293 001 FEB 18, 1987

AMINOCAPROIC ACID

INJECTABLE; INJECTION

> ADD >		**AMINOCAPROIC ACID IN PLASTIC CONTAINER**	
> ADD >	AP	ABBOTT LABS 250MG/ML¤	N70010 001 MAR 09, 1987
> ADD >			

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

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

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

> ADD >	AB	CHELSEA LABS	50MG;4MG¤	N71558 001 MAR 02, 1987
> ADD >				

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

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

ASPIRIN; MEPROBAMATE

TABLET; ORAL
MEPROGESIC

> ADD >				
> ADD >	AB	VITARINE	325MG;200MG¤	N89127 001 MAR 02, 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

@ SCHERING	0.2%	N14762 001

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL
BETAMETHASONE DIPROPIONATE

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

LOTION; TOPICAL
BETAMETHASONE DIPROPIONATE

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

OINTMENT; TOPICAL
BETAMETHASONE DIPROPIONATE

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

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE

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

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
BUPIVACAINE HCL

AP	ABBOTT LABS	0.25%¤	N70583 001 FEB 17, 1987

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPIVACAINE HCL

> ADD >	AP	ABBOTT LABS	0.25%¤	N70586 001 MAR 03, 1987
> ADD >				
	AP		0.25%¤	N70590 001 FEB 17, 1987
	AP		0.5%¤	N70584 001 FEB 17, 1987
> ADD >	AP		0.5%¤	N70597 001 MAR 03, 1987
> ADD >				
> ADD >	AP		0.5%¤	N70609 001 MAR 03, 1987
> ADD >				
> ADD >	AP		0.75%¤	N70585 001 MAR 03, 1987
> ADD >				
> ADD >	AP		0.75%¤	N70587 001 MAR 03, 1987
> ADD >				

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

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

CEFADROXIL

CAPSULE; ORAL

CEFADROXIL

> ADD >				
> ADD >	AB	ZENITH LABS	EQ 500MG BASE¤	N62766 001 MAR 03, 1987
> ADD >				

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

MS&D	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

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

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

	AB	BIOCRAFT LABS	EQ 250MG BASE¤	N62702 001 FEB 13, 1987
	AB		EQ 500MG BASE¤	N62702 002 FEB 13, 1987
> ADD >	AB	ZENITH LABS	EQ 250MG BASE¤	N61969 001
> ADD >	AB		EQ 500MG BASE¤	N61969 002

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

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN

AB	BIOCRAFT LABS	EQ 125MG BASE/5ML¤	N62703 001 FEB 13, 1987
AB		EQ 250MG BASE/5ML¤	N62703 002 FEB 13, 1987

KEFLEX

AB	LILLY	EQ 125MG BASE/5ML	N50406 001
AB		EQ 125MG BASE/5ML	N62117 002
AB		EQ 250MG BASE/5ML	N50406 002
AB		EQ 250MG BASE/5ML	N62117 003

TABLET; ORAL

KEFLET

LILLY	EQ 250MG BASE¤	N50440 003 FEB 26, 1987
	EQ 500MG BASE	N50440 001
	EQ 1GM BASE	N50440 002

/KEFLEX/ /LILLY/ /EQ 1GM BASE/ /N50440 002/

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

>_ADD_>		CEPHALOTHIN SODIUM W/ DEXTROSE IN PLASTIC CONTAINER		
>_ADD_>		TRAVENOL LABS	EQ 20MG BASE/ML¤	N62730 001
>_ADD_>				MAR 05, 1987
>_ADD_>			EQ 40MG BASE/ML¤	N62730 002
>_ADD_>				MAR 05, 1987

CEPHRADINE

CAPSULE; ORAL

		CEPHRADINE		
	AB	BIOCRAFT LABS	250MG¤	N62683 001
				JAN 09, 1987
	AB		500MG¤	N62683 002
				JAN 09, 1987
>_ADD_>	AB	ZENITH LABS	250MG¤	N62762 001
>_ADD_>				MAR 06, 1987
>_ADD_>	AB		500MG¤	N62762 002
>_ADD_>				MAR 06, 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		
	AP	@ SCHERING	100MG/ML	N08794 001

CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE

TABLET; ORAL

		CLONIDINE HCL AND CHLORTHALIDONE		
	AB	MYLAN PHARMS	15MG;0.1MG¤	N71323 001
				FEB 09, 1987
	AB		15MG;0.2MG¤	N71324 001
				FEB 09, 1987
	AB		15MG;0.3MG¤	N71325 001
				FEB 09, 1987
		COMBIPRES		
	AB	BOEHR INGEL	15MG;0.1MG	N17503 001
	AB		15MG;0.2MG	N17503 002
	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

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

		CLONIDINE HCL		
>_ADD_>	AB	BOLAR PHARM	0.1MG¤	N70395 001
>_ADD_>				MAR 23, 1987
>_ADD_>	AB		0.2MG¤	N70396 001
>_ADD_>				MAR 23, 1987
>_ADD_>	AB		0.3MG¤	N70397 001
>_ADD_>				MAR 23, 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		
>_ADD_>	AB	@ ABBOTT LABS	3.75MG	N17105 001
>_ADD_>	AB	@	7.5MG	N17105 002
>_ADD_>	AB	@	15MG	N17105 003

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

> ADD >		**PHERAZINE VC W/ CODEINE**		
> ADD >	AA	HALSEY DRUG	10MG/5ML;5MG/5ML; 6.25MG/5ML¤	N88870 001 MAR 02, 1987
> ADD >				
> ADD >				

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

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

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

		DEXAMETHASONE SODIUM PHOSPHATE		
> ADD >	AP	QUAD PHARMS	EQ 4MG PHOSPHATE/ML¤	N89280 001 MAR 18, 1987
> ADD >				
> ADD >	AP		EQ 10MG PHOSPHATE/ML¤	N89281 001 MAR 18, 1987
> ADD >				
> ADD >	AP		EQ 20MG PHOSPHATE/ML¤	N89282 001 MAR 18, 1987
> ADD >				
> ADD >	AP		EQ 24MG PHOSPHATE/ML¤	N89372 001 MAR 18, 1987
> ADD >				

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

> ADD >		**PHERAZINE DM**		
> ADD >	AA	HALSEY DRUG	15MG/5ML;6.25MG/5ML¤	N88913 001 MAR 02, 1987
> ADD >				

DIAZEPAM

TABLET; ORAL

	DIAZEPAM		
AB	DANBURY PHARMA	2MG¤	N71134 001 FEB 03, 1987
AB		5MG¤	N71135 001 FEB 03, 1987
AB		10MG¤	N71136 001 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		
	BOEHR INGEL	50MG¤	N12836 004 FEB 06, 1987
		75MG¤	N12836 005 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
AB	SUPERPHARM	EQ 100MG BASE¤	N70940 001 FEB 09, 1987
AB		EQ 150MG BASE¤	N70941 001 FEB 09, 1987

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

> ADD >		**DOPAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER**		
> ADD >	AP	TRAVENOL LABS	80MG/100ML¤	N19615 001
> ADD >				MAR 27, 1987
> ADD >	AP		160MG/100ML¤	N19615 002
> ADD >				MAR 27, 1987
> ADD >	AP		320MG/100ML¤	N19615 003
> ADD >				MAR 27, 1987
> ADD >			640MG/100ML¤	N19615 004
> ADD >				MAR 27, 1987

DOXEPIN HYDRCHLORIDE

CAPSULE; ORAL

		DOXEPIN HCL		
> ADD >	AB	CHELSEA LABS	EQ 10MG BASE¤	N70952 001
> ADD >				MAR 04, 1987
> ADD >	AB	CORD LABS	EQ 10MG BASE¤	N71487 001
> ADD >				MAR 02, 1987
> ADD >	AB		EQ 100MG BASE¤	N71562 001
> ADD >				MAR 02, 1987

ERYTHYROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

		ERYTHROMYCIN ETHYLSUCCINATE		
> ADD >	AB	NASKA PHARMA	EQ 400MG BASE/5ML¤	N62674 001
> ADD >				MAR 10, 1987

ESTRADIOL CYPIONATE

INJECTABLE; INJECTION

		ESTRADIOL CYPIONATE		
	AO	QUAD PHARMS	5MG/ML¤	N89310 001
				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

ETHINYL ESTRADIOL; NORETHINDRONE

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

FLUOROURACIL

INJECTABLE; INJECTION

		FLUOROURACIL		
	AP	LYPHOMED	50MG/ML¤	N89428 001
				JAN 12, 1987
> ADD >	AP		50MG/ML¤	N89519 001
> ADD >				MAR 12, 1987
	AP	QUAD PHARMS	50MG/ML¤	N89368 001
				FEB 03, 1987
	AP		50MG/ML¤	N89455 001
				FEB 03, 1987
> ADD >	AP	SOLOPAK LABS	50MG/ML¤	N89434 001
> ADD >				MAR 26, 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

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION
GLUCAGON

> ADD >	AP	LILLY	EQ 1MG BASE/VIAL	N12122 001
> ADD >	AP		EQ 10MG BASE/VIAL	N12122 002
> ADD >	AP	QUAD PHARMS	EQ 1MG BASE/VIAL¤	N71022 001 MAR 04, 1987
> ADD >				
> ADD >	AP		EQ 10MG BASE/VIAL¤	N71023 001 MAR 04, 1987
> ADD >				

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	DANBURY PHARMA	0.5MG¤	N70981 001 MAR 06, 1987
> ADD >				
> ADD >	AB		1MG¤	N70982 001 MAR 06, 1987
> ADD >				
> ADD >	AB		2MG¤	N70983 001 MAR 06, 1987
> ADD >				
> ADD >	AB		5MG¤	N70984 001 MAR 06, 1987
> ADD >				
	AB	QUANTUM PHARMCS	0.5MG¤	N71255 001 FEB 17, 1987
	AB		1MG¤	N71269 001 FEB 17, 1987
	AB		2MG¤	N71256 001 FEB 17, 1987
	AB		5MG¤	N71257 001 FEB 17, 1987
	AB	ROXANE LABS	0.5MG¤	N71128 001 FEB 17, 1987
	AB		1MG¤	N71129 001 FEB 17, 1987
	AB		2MG¤	N71130 001 FEB 17, 1987
	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

AT	@ MILES PHARMS	3%	N17405 001

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

AB	SUPERPHARM	25MG;25MG¤	N89200 001 FEB 09, 1987
AB		50MG;50MG¤	N89201 001 FEB 09, 1987

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

> ADD >	AB	INVAMED	15MG;250MG¤	N70829 001 MAR 09, 1987
> ADD >				
> ADD >	AB		25MG;250MG¤	N70830 001 MAR 09, 1987
> ADD >				
	AB	PAR PHARM	15MG;250MG¤	N70616 001 FEB 02, 1987
	AB		25MG;250MG¤	N70612 001 FEB 02, 1987
	AB		30MG;500MG¤	N70613 001 FEB 02, 1987
	AB		50MG;500MG¤	N70614 001 FEB 02, 1987

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL & HYDROCHLOROTHIAZIDE

> ADD >	AB	DURAMED PHARMS	25MG;40MG¤	N71126 001 MAR 02, 1987
> ADD >				
> ADD >	AB		25MG;80MG¤	N71127 001 MAR 02, 1987
> ADD >				

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

> ADD >	AB	MYLAN PHARMS	25MG;40MG¤	N70946 001 MAR 04, 1987
> ADD >				

HYDROCORTISONE

OINTMENT; TOPICAL
HYDROCORTISONE

	AT	PHARMADERM	1%¤	N88842 001 FEB 09, 1987

HYDROCORTISONE BUTYRATE

LOTION; TOPICAL
LOCOID

		GIST BROCADES	0.1%¤	N19116 001 FEB 25, 1987

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
HYDROXYPROGESTERONE 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

		@ 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

	AB	BARR LABS	800MG¤	N71448 001 FEB 18, 1987
> ADD >	AB	HALSEY DRUG	300MG¤	N71028 001 MAR 23, 1987
> ADD >	AB		400MG¤	N71029 001 MAR 23, 1987
> ADD >	AB		600MG¤	N71030 001 MAR 23, 1987

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

	AB	MUTUAL PHARM	25MG¤	N70899 001 FEB 09, 1987
	AB		50MG¤	N70900 001 FEB 09, 1987
> ADD >	AB	SIDMAK LABS	25MG¤	N71148 001 MAR 18, 1987
> ADD >	AB		50MG¤	N71149 001 MAR 18, 1987

SUSPENSION; ORAL
INDOCIN

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

INDOMETHACIN

> ADD >	AB	ROXANE LABS	25MG/5ML¤	N71412 001 MAR 18, 1987

IRON DEXTRAN COMPLEX

INJECTABLE; INJECTION

> DLT >		~~IMFERON~~		
> DLT >	~~AP~~	~~MERRELL DOW~~	~~EQ 50MG IRON/ML~~	~~N10787 002~~
> ADD >		IMFERON		
> ADD >	AP	FISONS	EQ 50MG IRON/ML	N10787 002

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

	AB	BARR LABS	5MG	N86166 002 SEP 19, 1986
	AB		10MG	N86169 001 SEP 19, 1986
	AB		20MG	N86167 001 SEP 19, 1986

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

AB	SUPERPHARM	5MG¤	N89190 001	FEB 17, 1987
AB		10MG¤	N89191 001	FEB 17, 1987
AB		20MG¤	N89192 001	FEB 17, 1987

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX

> ADD > > ADD >	BRISTOL LABS	EQ 500MG BASE¤	N62726 001	MAR 06, 1987

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

AP	ELKINS SINN	EQ 50MG BASE/VIAL¤	N70480 001	JAN 02, 1987
> ADD > > ADD > AP	QUAD PHARMS	EQ 50MG BASE/VIAL¤	N89496 001	MAR 05, 1987

POWDER FOR RECONSTITUTION; ORAL
LEUCOVORIN CALCIUM

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

TABLET; ORAL
LEUCOVORIN CALCIUM

> ADD > > ADD >	LEDERLE LABS	EQ 15MG BASE¤	N71104 001	MAR 04, 1987

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

> ADD > > ADD > AB	BOLAR PHARM	300MG¤	N70407 001	MAR 19, 1987

LORAZEPAM

TABLET; ORAL
LORAZEPAM

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

LORAZEPAM

TABLET; ORAL
LORAZEPAM

> ADD > > ADD > AB	WATSON LABS	0.5MG¤	N71086 001	MAR 23, 1987
> ADD > > ADD > AB		1MG¤	N71087 001	MAR 23, 1987
> ADD > > ADD > AB		2MG¤	N71088 001	MAR 23, 1987

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

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

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

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

METHOTREXATE SODIUM

INJECTABLE; INJECTION

> ADD >		ABITREXATE		
> ADD >	AP	INTL PHARM	EQ 25MG BASE/ML¤	N89161 001 MAR 10, 1987
> ADD >				

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

INJECTABLE; INJECTION

		METOCLOPRAMIDE HCL		
> ADD >	AP	SOLOPAK LABS	EQ 10MG BASE/2ML¤	N70622 001 MAR 02, 1987
> ADD >				
> ADD >	AP		EQ 10MG BASE/2ML¤	N70623 001 MAR 02, 1987
> ADD >				

SYRUP; ORAL

> ADD >		METOCLOPRAMIDE HCL		
> ADD >	AA	MY K LABS	EQ 5MG BASE/5ML¤	N70949 001 MAR 06, 1987
> ADD >				
		REGLAN		
> ADD >	AA	ROBINS	EQ 5MG BASE/5ML	N18821 001 MAR 25, 1983

TABLET; ORAL

		METOCLOPRAMIDE HCL		
	AB	BARR LABS	EQ 10MG BASE¤	N70660 001 FEB 10, 1987
> ADD >	AB	BOLAR PHARM	EQ 10MG BASE¤	N70363 001 MAR 02, 1987
> ADD >				
	AB	INVAMED	EQ 10MG BASE¤	N70850 001 FEB 03, 1987
	AB	MARTEC PHARMS	EQ 10MG BASE¤	N70598 001 FEB 02, 1987

METRIZAMIDE

INJECTABLE; INJECTION

		AMIPAQUE		
		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

MINOXIDIL

TABLET; ORAL

		LONITEN		
> ADD >	AB	UPJOHN	2.5MG	N18154 001
> ADD >	AB		10MG	N18154 003
> ADD >		MINODYL		
> ADD >	AB	QUANTUM PHARMCS	10MG¤	N71534 001 MAR 19, 1987
> ADD >				
> ADD >		MINOXIDIL		
> ADD >	AB	DANBURY PHARMA	2.5MG¤	N71344 001 MAR 03, 1987
> ADD >				
> ADD >	AB		10MG¤	N71345 001 MAR 03, 1987
> ADD >				

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

NAPROXEN

SUSPENSION; ORAL

> ADD >		NAPROSYN		
> ADD >		SYNTEX	25MG/ML¤	N18965 001 MAR 23, 1987
> ADD >				

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

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN-TRIAMCINOLONE ACETONIDE

> ADD >	AT	THAMES PHARMA	100,000 UNITS/GM;0.1%¤	N62347 001 MAR 30, 1987
> ADD >				

OINTMENT; TOPICAL
> ADD > MYKACET

> ADD >	AT	NMC LABS	100,000 UNITS/GM;0.1%¤	N62733 001 MAR 09, 1987
> ADD >				

OXAZEPAM

TABLET; ORAL
OXAZEPAM

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

SERAX

AB	WYETH	15MG	N15539 008

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
> ADD > PHERAZINE VC

> ADD >	AA	HALSEY DRUG	5MG/5ML;6.25MG/5ML¤	N88868 001 MAR 02, 1987
> ADD >				

PHENYTOIN SODIUM

INJECTABLE; INJECTION
PHENYTOIN SODIUM

> ADD >	AP	ABBOTT LABS	50MG/ML¤	N89521 001 MAR 17, 1987
> ADD >				

POTASSIUM CHLORIDE

CAPSULE, CONTROLLED RELEASE; ORAL
MICRO-K 10

BC	ROBINS	10MEQ	N18238 002 MAY 14, 1984

POTASSIUM CHLORIDE

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

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
> ADD >	AB	COPLEY PHARM	750MG¤	N89438 001 MAR 23, 1987
> ADD >				
	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

CAPSULE, CONTROLLED RELEASE; ORAL
INDERAL LA

> ADD >	AYERST LABS	60MG¤	N18553 004 MAR 18, 1987
> ADD >			

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

> ADD >	AB	BOLAR PHARM	10MG¤	N70378 001
> ADD >				MAR 19, 1987
> ADD >	AB		20MG¤	N70379 001
> ADD >				MAR 19, 1987
> ADD >	AB		40MG¤	N70380 001
> ADD >				MAR 19, 1987
> ADD >	AB		60MG¤	N70381 001
> ADD >				MAR 19, 1987
> ADD >	AB		80MG¤	N70382 001
> ADD >				MAR 19, 1987
	AB	CHELSEA LABS	60MG¤	N70143 001
				JAN 15, 1987

QUAZEPAM

TABLET; ORAL
DORMALIN

	SCHERING	7.5MG¤	N18708 003
			FEB 26, 1987

QUINDINE GLUCONATE

TABLET, CONTROLLED RELEASE; ORAL
QUINDINE GLUCONATE

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

> ADD > SOMATROPIN, BIOSYNTHETIC

> ADD > INJECTABLE; INJECTION
> ADD > HUMATROPE
> ADD > LILLY 5MG/VIAL¤ N19640 004
> ADD > MAR 08, 1987

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

> DLT >	~~AA~~	~~SUPERPHARM~~	~~25MG~~	~~N89364 001~~
> DLT >				~~NOV 07, 1986~~
> ADD >	AB	SUPERPHARM	25MG	N89364 001
> ADD >				NOV 07, 1986

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
SULFAMETHOXAZOLE AND TRIMETHOPRIM

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

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

> DLT >	~~AB~~	~~PLANTEX~~	~~800MG;160MG¤~~	~~N70037 001~~
> DLT >				~~JUN 02, 1987 : SEP 19, 1985~~
> ADD >	AB	PLANTEX	800MG;160MG¤	N70037 001
> ADD >				SEP 19, 1985

SULFAMETHOXAZOLE AND TRIMETHOPRIM SINGLE STRENGTH

> DLT >	~~AB~~	~~PLANTEX~~	~~400MG;80MG¤~~	~~N70030 001~~
> DLT >				~~JUN 02, 1987 : SEP 19, 1985~~
> ADD >	AB	PLANTEX	400MG;80MG¤	N70030 001
> ADD >				SEP 19, 1985

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

@ ABBOTT LABS	165MG	N06044 003

TECHNETIUM TC-99M, MEBROFENIN KIT

INJECTABLE; INJECTION
CHOLETEC

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

TEMAZEPAM

CAPSULE; ORAL
TEMAZEPAM

> ADD >	AB	BOLAR PHARM	15MG¤	N70383 001
> ADD >				MAR 23, 1987
> ADD >	AB		30MG¤	N70384 001
> ADD >				MAR 23, 1987

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

> ADD >	AB	BARR LABS	50MG¤	N71258 001
> ADD >				MAR 25, 1987
> ADD >	AB		100MG¤	N71196 001
> ADD >				MAR 25, 1987

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

> ADD >		LYPHOCIN		
> ADD >	AP	LYPHOMED	EQ 500MG BASE/VIAL¤	N62663 001
> ADD >				MAR 17, 1987
		VANCOCIN HCL		
> ADD >	AP	LILLY	EQ 500MG BASE/VIAL¤	N62716 001
> ADD >				MAR 13, 1987
> ADD >			EQ 1GM BASE/VIAL¤	N62716 002
> ADD >				MAR 13, 1987

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
VERAPAMIL HCL

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

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

> ADD >	AP	QUAD PHARM	1MG/ML¤	N89311 001
> ADD >				MAR 23, 1987

VINCRISTINE SULFATE

INJECTABLE; INJECTION
VINCRISTINE SULFATE

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

WARFARIN POTASSIUM

TABLET; ORAL
ATHROMBIN-K

		@ PURDUE FRDRK	2MG	N11771 007
		@	10MG	N11771 005
		@	25MG	N11771 006

WARFARIN SODIUM

TABLET; ORAL
ATHROMBIN

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

XYLOSE

POWDER; ORAL

> ADD >		XYLOSE		
> ADD >	AA	LYNE LABS	25GM/BOT¤	N18856 001
> ADD >				MAR 26, 1987
		XYLO-PFAN		
> ADD >	AA	ADRIA LABS	25GM/BOT	N17605 001

> ADD > ZIDOVUDINE

CAPSULE; ORAL
RETROVIR

> ADD >		BURROUGHS WELLC	100MG¤	N19655 001
> ADD >				MAR 19, 1987

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN
> ADD > UPSHER SMITH 325MG N18337 002

ASPIRIN

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

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
> ADD > CHLORHEXIDINE GLUCONATE
> ADD > KENDALL 4%¤ N19490 001
> ADD > MAR 27, 1987

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
INTERPHARM 200MG¤ N71333 001
FEB 17, 1987
PUREPAC 200MG¤ N71664 001
FEB 03, 1987

IBUPROFEN

TABLET; ORAL
NEUVIL
LUCHEM PHARMS 200MG¤ N71144 001
JAN 20, 1987
TRENDAR
WHITEHALL LABS 200MG N18989 002
JUL 10, 1986

POVIDONE-IODINE

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

NO JANUARY - MARCH 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 PHARM	18470 001 OCT 31, 1986	ODE OCT 31, 1993
SOMATROPIN, BIOSYNTHETIC 5MG/VIAL	HUMATROPE INJECTABLE; INJECTION	LILLY	19640 004 MAR 08, 1987	ODE MAR 08, 1994
ZIDOVUDINE 100MG	RETROVIR CAPSULE; ORAL	BURROUGHS WELLC	19655 001 MAR 19, 1987	ODE MAR 19, 1994

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

NO MARCH 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
CEPHALEXIN (TABLET AND CAPSULE)	AUG 13, 1986	MAR 19, 1987
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
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	500MG 2.5MG	85 P-0439/ CP002	KING AND SPAULDING	NEW STRENGTH	APPROVED MAR 18, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	500MG 7.5MG	85 P-0439/CP	KING AND SPAULDING	NEW STRENGTH	APPROVED MAR 17, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE CAPSULE; ORAL	650MG 7.5MG	85 P-0390/CP	UAD LABS	NEW STRENGTH NEW DOSAGE FORM	APPROVED MAR 17, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	650MG 7.5MG	85 P-0390/CP	UAD LABS	NEW STRENGTH NEW DOSAGE FORM	APPROVED MAR 17, 1987

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	750MG 7.5MG	85 P-0169/PRC*	KNOLL PHARM	NEW STRENGTH	APPROVED MAR 13, 1987
BRETYLIUM TOSYLATE INJECTABLE; INJECTION	200MG/ML (10ML/CONTAINER)	85 P-0546/CP	INTL MEDTN 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 LABS	NEW STRENGTH	APPROVED JAN 09, 1987
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 25MG BASE/VIAL	86 P-0240/CP	BURROUGHS WELLC	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

*ORIGINAL PETITION DENIED NOV 07, 1985; PETITION FOR RECONSIDERATION APPROVED MAR 13, 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	NEW STRENGTH	APPROVED JAN 16, 1987
LORAZEPAM SOFT GELATIN CAPSULE; ORAL	0.5MG 1MG 2MG	87 P-0037/CP	APPLIED LABORATORIES	NEW DOSAGE FORM	APPROVED MAR 10, 1987
METHYLDOPATE HYDROCHLORIDE IN 5% DEXTROSE INJECTABLE; INJECTION	2.5MG/ML (100ML/CONTAINER)	86 P-0410/ CP0002	KING AND SPAULDING	NEW STRENGTH	APPROVED MAR 10, 1987
METHYLDOPATE HYDROCHLORIDE IN 5% DEXTROSE INJECTABLE; INJECTION	5MG/ML (100ML/CONTAINER)	86 P-0410/ CP0003	KING AND SPAULDING	NEW STRENGTH	APPROVED MAR 10, 1987
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	0.5MG/ML (100 ML/CONTAINER)	86 P-0099/ CP0004	ABBOTT LABS	NEW STRENGTH	APPROVED FEB 02, 1987
SODIUM NITROPRUSSIDE INJECTABLE; INJECTION	25MG/ML (2ML/VIAL)	87 P-0039/CP	ABBOTT LABS	NEW DOSAGE FORM	APPROVED MAR 10, 1987
THEOPHYLLINE CAPSULE, CONTROLLED RELEASE; ORAL	400MG	86 P-0471/ CP0002	SEARLE RESEARCH AND DEVELOPMENT	NEW STRENGTH	APPROVED MAR 10, 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 DOSING SCHEDULE

D-13	INCREASED MAXIMUM DAILY DOSAGE RECOMMENDATION

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
I-62	TREATMENT OF JUVENILE ARTHRITIS

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		
				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
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
12836 004	PERSANTINE; DIPYRIDAMOLE				I-49	DEC 22, 1989
12836 005	PERSANTINE; DIPYRIDAMOLE				I-49	DEC 22, 1989
17820 002	DOBUTREX; DOBUTAMINE HYDROCHLORIDE	3987200	OCT 19, 1993	U-11		
19386 002	BREVIBLOC; ESMOLOL HYDROCHLORIDE	4593119	JUN 03, 2003		NCE	DEC 31, 1991
		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		

SEE PAGE iv OF INTRODUCTION (BOLD-FACED) FOR A CHANGE IN FORMAT TO THIS DATA

SEE PAGE iv OF INTRODUCTION (BOLD-FACED) FOR A CHANGE IN FORMAT TO THIS DATA

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		
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			
		3755427	AUG 28, 1990		NCE	DEC 31, 1991
18123 001	FACTREL; GONADORELIN HYDROCHLORIDE	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

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	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		
	18677 001	CESAMET; NABILONE	4087545	MAY 02, 1995	U-7		
			3928598	DEC 23, 1992	U-6		
			3920809	NOV 18, 1992		NCE	DEC 26, 1990
>ADD>	17581 002	NAPROSYN; NAPROXEN	3998966	DEC 21, 1993		I-62	MAR 23, 1990
>ADD>			3904682	SEP 09, 1992		D-13	MAR 23, 1990
>ADD>	17581 003	NAPROSYN; NAPROXEN	3998966	DEC 21, 1993		I-62	MAR 23, 1990
>ADD>			3904682	SEP 09, 1992		D-13	MAR 23, 1990
>ADD>	17581 004	NAPROSYN; NAPROXEN	3998966	DEC 21, 1993		I-62	MAR 23, 1990
>ADD>			3904682	SEP 09, 1992		D-13	MAR 23, 1990
>ADD>	18965 001	NAPROSYN; NAPROXEN	4009197	SEP 09, 1992			
>ADD>			4001301	SEP 09, 1992			
>ADD>			3998966	DEC 21, 1993			
>ADD>			3904682	SEP 09, 1992		NDF	MAR 23, 1990
	19384 002	NOROXIN; NORFLOXACIN	4639458	JAN 27, 2004			
	17031 001	OVRETTE; NORGESTREL	3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
>ADD>	18553 004	INDERAL LA; PROPRANOLOL HYDROCHLORIDE	4138475	FEB 06, 1996			
	18708 003	DORMALIN; QUAZEPAM	3920818	NOV 18, 1992			
			3845039	OCT 29, 1991		NCE	DEC 27, 1990
	18859 001	VIRAZOLE; RIBAVIRIN	4211771	JUL 08, 1999		NCE	DEC 31, 1990
	19518 002	EXTRA-STRENGTH AIM; SODIUM MONOFLUOROPHOSPHATE				NS	AUG 06, 1989
>ADD>	19640 004	HUMATROPE; SOMATROPIN, BIOSYNTHETIC				ODE	MAR 08, 1994
	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
	19415 002	METRODIN; UROFOLLITROPIN				NE	SEP 18, 1989
	14103 003	ONCOVIN; VINCRISTINE SULFATE	4619935	OCT 28, 2003			
>ADD>	19655 001	RETROVIR; ZIDOVUDINE				NCE	MAR 19, 1992
>ADD>						ODE	MAR 19, 1994

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