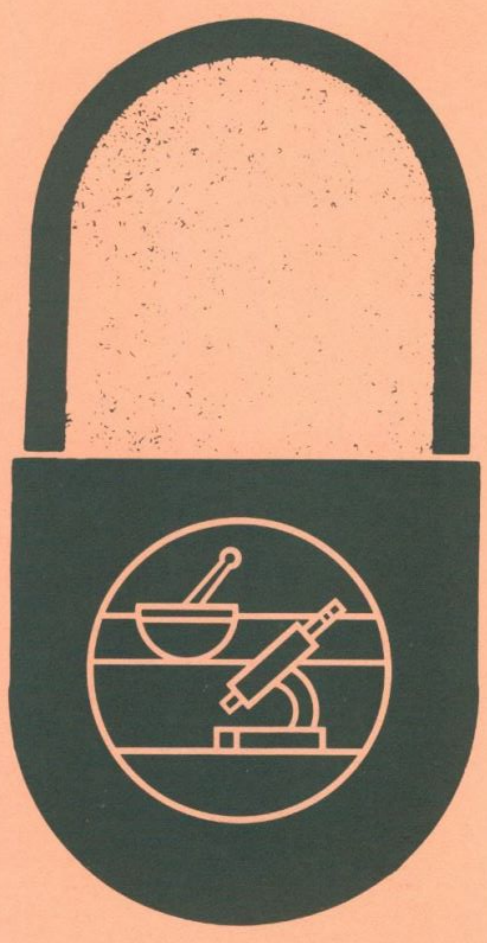
CUMULATIVE SUPPLEMENT 6

JAN'87-JUN'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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JUNE 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 " 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 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 reflux 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
WILLIAM H RORER INC	RORER PHARMACEUTICAL CORP SUB RORER GROUP	RORER PHARM
USV (PR) DEVELOPMENT CORPORATION	RORER PHARMACEUTICAL CORP SUB RORER GROUP	RORER PHARM
USV LABORATORIES INC	RORER PHARMACEUTICAL CORP SUB RORER GROUP	RORER PHARM
USV PHARMACEUTICAL CORP	RORER PHARMACEUTICAL CORP SUB RORER GROUP	RORER PHARM

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 CHANGE OF A THERAPEUTIC EQUIVALENCE CODE FOR A DRUG ENTITY

This section explains the procedures the Agency will use when, in response to a petition or on its own initiative, it is considering a change in the therapeutic equivalence code for approved multisource drug products. Such changes will generally occur when the Agency becomes aware of new scientific information affecting therapeutic equivalence. These procedures will be used when all drug products found in the "Drug Product List" under a specific drug entity and dosage form are being considered for a change. The change may be from the code signifying that the drug does not present a bioequivalence problem drug (e.g., AA) to a code signifying a bioequivalence problem (e.g., BP), or vice versa. A change of a single product code from BP to AB as a result of a bioequivalence study is not applicable in this section.

This section lists those drug entities that are actively being considered by the Agency for reclassification. Before making a change in the code, the Agency will announce in this section of the Cumulative Supplement that it is considering the change and will invite comment. Comments, along with scientific data, may be sent to the Division of Bioequivalence, HFN-250, Room 17B06, 5600 Fishers Lane, Rockville, MD 20857. The comment period will generally be 60 days in length, and the closing date for comments will be listed in the description of the proposed change for each drug entity.

The most useful type of scientific data is an in vivo bioavailability/ bioequivalence study conducted on batches of the subject drug. These submissions should present a full description of the analytical procedures and equipment used, a validation of the analytical methodology, including the standard curve, a description of the method of calculating results, and a description of the pharmacokinetic and statistical models used in analyzing the data. Anecdotal or testimonial information is the least useful to the Agency, and such submissions are discouraged. However, copies of supporting reports published in the scientific literature or unpublished material are welcome.

The Agency is currently considering a change in therapeutic equivalence evaluation for the following drug(s):

Benztropine mesylate:

The Agency initially did not classify benztropine mesylate as having an actual or potential bioequivalence problem. (42 FR 1624, January 7, 1977). Benztropine mesylate tablets (Cogentin) is a DESI drug product that was raised to the effective status on November 7, 1970 (35 FR 211). It remained single source until January 1984. At that time, the Agency reviewed its status regarding a potential bioequivalence problem. Based principally on a published article, Coyle, J.T., and Tune, L.E. "Acute Extrapyramidal Side Effects: Serum Levels of Neuroleptics and Anticholinergics," Psychopharmacology, 75:9-15 (1981), the Agency decided that benztropine mesylate did present a potential bioequivalence problem because of the possibility of nonlinear kinetics. As a result, an in vivo bioequivalence study was required to demonstrate bioequivalence and to gain approval of an ANDA.

Recently, two pharmaceutical firms have asked the Agency to change the therapeutic equivalence code for benztropine mesylate oral tablets from BP to AA. Although the Agency disagrees with the arguments on the basis that the requests were primarily legal and regulatory, the Agency used the opportunity to reassess the merits of its earlier decision. Upon a careful re-review of the article in question and another search of the literature, the Agency now believes that there is an insufficient basis upon which to evaluate benztropine mesylate as having a potential bioequivalence problem. In addition, one of the authors of the article has advised the Agency that he does not believe the data in the article provide a basis for concluding that benztropine mesylate displays nonlinear kinetics. In addition, the drug is freely soluble in water and does not generally meet the criteria, described in 21 CFR 320.52, for a drug posing a bioequivalence problem.

The Agency requests that interested parties submit comments with respect to the Agency's proposal to change the therapeutic equivalence code for listed benztropine mesylate oral tablets from BP to AA. We request that such comments be received no later than September 30, 1987.

1.10 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)	MAR '87
DRUG PRODUCTS LISTED	8957	9183
SINGLE SOURCE	2103 (23.5%)	2095 (22.8%)
MULTISOURCE(1)	6854 (76.5%)	7088 (77.2%)
THERAPEUTICALLY EQUIVALENT	5838 (65.2%)	6093 (66.4%)
NOT THERAPEUTICALLY EQUIVALENT	967 (10.8%)	950 (10.3%)
EXCEPTIONS(2)	49 (0.5%)	45 (0.5%)
NEW MOLECULAR ENTITIES APPROVED	-	2
NUMBER OF APPLICANTS	333	334

B. ACTIVITY FOR SUPPLEMENT NUMBER 6

	APR '87	MAY '87	JUN '87	CUMULATIVE
DRUG PRODUCTS ADDED:	62	47	61	170
NEWLY APPROVED	62	47	61	170
DESI EFFECTIVE	0	0	0	0
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	62	47	61	170
SINGLE SOURCE PRODUCTS APPROVED	8	10	3	21
MULTISOURCE DRUG PRODUCTS APPROVED	54	37	58	149
NEW MOLECULAR ENTITIES APPROVED:	1	0	0	1
AS THE ENTITY	0	0	0	0
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	1	0	0	1

(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)

ACETAMINOPHEN

INJECTABLE; INJECTION
INJECTAPAP
∂ MCNEIL PHARM — 100MG/ML — N17785 001 MAR 07, 1986

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
AB MIKART — 325MG;50MG;40MG — N89175 001 JAN 21, 1987

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 2
AA AM THERPTCS — 300MG;15MG — N89478 001 MAR 03, 1987
AA — 300MG;15MG — N89481 001 MAR 03, 1987

ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 3
AA AM THERPTCS — 300MG;30MG — N89479 001 MAR 03, 1987
AA — 300MG;30MG — N89482 001 MAR 03, 1987

ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 4
AA AM THERPTCS — 300MG;60MG — N89480 001 MAR 03, 1987
AA — 300MG;60MG — N89483 001 MAR 03, 1987

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
ANEXSIA-D
AA BEECHAM LABS — 500MG;5MG — N89160 001 APR 23, 1987

HYDROCODONE BITARTRATE AND ACETAMINOPHEN
> ADD > AA HALSEY DRUG — 500MG;5MG — N89554 001 JUN 12, 1987
> ADD >
AA PHARM BASICS — 500MG;5MG — N89290 001 MAY 29, 1987
AA — 500MG;5MG — N89291 001 MAY 29, 1987

/TYCODONE/
/AB/ /MCNEIL/PHARM/ /500MG;5MG/ /N89385/001/ /AUG/27,/1986/

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
TYCOLET
AA MCNEIL PHARM — 500MG;5MG — N89385 001 AUG 27, 1986

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL
OXYCODONE HCL AND ACETAMINOPHEN
/AA/ /ROXANE/LABS/ /325MG;5MG/ /N87003/001/
ROXICET
AA ROXANE LABS — 325MG;5MG — N87003 001

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
AB PUREPAC PHARM — 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
AN SCHERING — EQ 0.5% BASE — N19243 001 JAN 14, 1987
EQ 0.083% BASE — N19243 002 JAN 14, 1987

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

SYRUP; ORAL
PROVENTIL
> ADD > AA SCHERING — EQ 2MG BASE/5ML — N18062 001 JAN 19, 1983
> ADD >

ALBUTEROL SULFATE

SYRUP; ORAL

> ADD >		VENTOLIN		
> ADD >	AA	GLAXO	EQ 2MG BASE/5ML¤	N19621 001 JUN 10, 1987
> ADD >				

ALLOPURINOL

TABLET; ORAL

	ALLOPURINOL		
AB	MUTUAL PHARM	100MG¤	N71449 001 JAN 09, 1987
AB		300MG¤	N71450 001 JAN 09, 1987
	LOPURIN		
AB	BOOTS PHARMS	100MG¤	N71586 001 APR 02, 1987
AB		300MG¤	N71587 001 APR 02, 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

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

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/

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

	AMITRIPTYLINE HCL		
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		
AB	CHELSEA LABS	50MG;4MG¤	N71558 001 MAR 02, 1987

AMPHOTERICIN B

INJECTABLE; INJECTION

	AMPHOTERICIN B		
AP	LYPHOMED	50MG/VIAL¤	N62728 001 APR 13, 1987
	FUNGIZONE		
AP	SQUIBB	50MG/VIAL	N60517 001

AMPICILLIN SODIUM

INJECTABLE; INJECTION

	AMPICILLIN SODIUM		
AP	IBI SPA	EQ 250MG BASE/VIAL¤	N62719 001 MAY 12, 1987
AP		EQ 500MG BASE/VIAL¤	N62719 003 MAY 12, 1987
AP		EQ 1GM BASE/VIAL¤	N62719 002 MAY 12, 1987
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; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

		NORGESIC		
>ADD>	AB	RIKER LABS	385MG;30MG;25MG	N13416 003
>ADD>				OCT 27, 1982
		NORGESIC FORTE		
>ADD>	AB	RIKER LABS	770MG;60MG;50MG	N13416 004
>ADD>				OCT 27, 1982
>ADD>		**ORPHENGESIC**		
>ADD>	AB	PAR PHARM	385MG;30MG;25MG¤	N71642 001
>ADD>				JUN 23, 1987
>ADD>		**ORPHENGESIC FORTE**		
>ADD>	AB	PAR PHARM	770MG;60MG;50MG¤	N71643 001
>ADD>				JUN 23, 1987

ASPIRIN; MEPROBAMATE

TABLET; ORAL

		MEPROGESIC		
AB		VITARINE	325MG;200MG¤	N89127 001
				MAR 02, 1987
/AB/		/MEPROGESIC Q/ /QUANTUM PHARMCS/	/325MG;200MG/	/N88740 001/ /JUN 01, 1984/
		Q-GESIC		
AB		QUANTUM PHARMCS	325MG;200MG	N88740 001
				JUN 01, 1984

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

BACITRACIN

INJECTABLE; INJECTION

		BACITRACIN		
AP		QUAD PHARMS	10,000 UNITS/VIAL¤	N62696 001
				APR 17, 1987
AP			50,000 UNITS/VIAL¤	N62696 002
				APR 17, 1987
AP		UPJOHN	10,000 UNITS/VIAL	N60733 001

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
>ADD>	AB	THAMES PHARMA	EQ 0.05% BASE¤	N71143 001
>ADD>				JUN 17, 1987
		DIPROLENE AF		
BX		SCHERING	EQ 0.05% BASE¤	N19555 001
				APR 27, 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

BETAMETHASONE VALERATE

CREAM; TOPICAL

		BETAMETHASONE VALERATE		
AB		PHARMAFAIR	EQ 0.1% BASE¤	N70485 001
				MAY 29, 1987

LOTION; TOPICAL

		BETAMETHASONE VALERATE		
AB		PHARMAFAIR	EQ 0.1% BASE¤	N70484 001
				MAY 29, 1987

OINTMENT; TOPICAL

		BETAMETHASONE VALERATE		
AB		PHARMAFAIR	EQ 0.1% BASE¤	N70486 001
				MAY 29, 1987

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

		BLENOXANE		
		BRISTOL LABS	EQ 15 UNITS BASE/VIAL	N50443 001

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
BLENOXANE
/NIPPON/KAYAKU/ /EQ/15/UNITS/BASE/VIAL/ /N61843/001/

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
AP		0.25%¤	N70586 001 MAR 03, 1987
AP		0.25%¤	N70590 001 FEB 17, 1987
AP		0.5%¤	N70584 001 FEB 17, 1986
AP		0.5%¤	N70597 001 MAR 03, 1987
AP		0.5%¤	N70609 001 MAR 03, 1987
AP		0.75%¤	N70585 001 MAR 03, 1987
AP		0.75%¤	N70587 001 MAR 03, 1987

SENSORCAINE

AP	ASTRA PHARM PRODS	0.75%¤	N71202 001 APR 15, 1987

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION
CALCIUM GLUCEPTATE

AP	LYPHOMED	EQ 90MG CALCIUM/5ML¤	N89373 001 APR 30, 1987

CARBAMAZEPINE

TABLET; ORAL
CARBAMAZEPINE

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

CEFADROXIL

CAPSULE; ORAL
CEFADROXIL

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

TABLET; ORAL
CEFADROXIL

AB	ZENITH LABS	EQ 1GM BASE¤	N62774 001 APR 08, 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

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

ROCHE	EQ 500MG BASE/VIAL¤	N62654 001 APR 30, 1987
	EQ 1GM BASE/VIAL¤	N62654 002 APR 30, 1987
	EQ 2GM BASE/VIAL¤	N62654 003 APR 30, 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

> ADD >	AB	BARR LABS	EQ 250MG BASE¤	N62773 001
> ADD >				JUN 26, 1987
	AB		EQ 500MG BASE¤	N62775 001
				APR 22, 1987
	AB	BIOCRAFT LABS	EQ 250MG BASE¤	N62702 001
				FEB 13, 1987
	AB		EQ 500MG BASE¤	N62702 002
				FEB 13, 1987
> ADD >	AB	MJ PHARMS	EQ 250MG BASE¤	N62791 001
> ADD >				JUN 11, 1987
> ADD >	AB		EQ 500MG BASE¤	N62791 002
> ADD >				JUN 11, 1987
	AB	NOVOPHARM	EQ 250MG BASE¤	N62760 001
				APR 24, 1987
	AB		EQ 500MG BASE¤	N62761 001
				APR 24, 1987
	AB	PUREPAC PHARM	EQ 250MG BASE¤	N62809 001
				APR 22, 1987
	AB		EQ 500MG BASE¤	N62809 002
				APR 22, 1987
	AB	ZENITH LABS	EQ 250MG BASE¤	N61969 001
	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

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL
CEPHALEXIN

> ADD >	AB	NOVOPHARM	EQ 250MG BASE/5ML¤	N62768 001
> ADD >				JUN 16, 1987
> ADD >	AB		EQ 125MG BASE/5ML¤	N62767 001
		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
CEPHALOTHIN SODIUM

> ADD >	AP	LYPHOMED	EQ 1GM BASE/VIAL¤	N62666 002
> ADD >				JUN 10, 1987
> ADD >	AP		EQ 2GM BASE/VIAL¤	N62666 001
> ADD >				JUN 10, 1987

CEPHALOTHIN SODIUM W/ DEXTROSE IN PLASTIC CONTAINER

TRAVENOL LABS	EQ 20MG BASE/ML¤	N62730 001	MAR 05, 1987
	EQ 40MG BASE/ML¤	N62730 002	MAR 05, 1987

CEPHRADINE

CAPSULE; ORAL
CEPHRADINE

	AB	BIOCRAFT LABS	250MG¤	N62683 001
				JAN 09, 1987
	AB		500MG¤	N62683 002
				JAN 09, 1987
	AB	ZENITH LABS	250MG¤	N62762 001
				MAR 06, 1987
	AB		500MG¤	N62762 002
				MAR 06, 1987

CEPHRADINE

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

TABLET; ORAL
CHLORTHALIDONE

>ADD>	AB	COLMED LABS	25MG¤	N89051 001 JUN 01, 1987
>ADD>	AB		50MG¤	N89052 001 JUN 01, 1987

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

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

AA	AMIDE PHARM	250MG¤	N88928 001	MAY 08, 1987

CHROMIC CHLORIDE

INJECTABLE; INJECTION
CHROMIC CHLORIDE

AP	LYPHOMED	EQ 0.004MG CHROMIUM/ML¤	N19271 001	MAY 05, 1987

CHROMIC CHLORIDE IN PLASTIC CONTAINER

AP	ABBOTT LABS	EQ 0.004MG CHROMIUM/ML	N18961 001	JUN 26, 1986

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

AB	BOLAR PHARM	0.1MG¤	N70395 001	MAR 23, 1987
AB		0.2MG¤	N70396 001	MAR 23, 1987
AB		0.3MG¤	N70397 001	MAR 23, 1987
>ADD>	AB	MYLAN PHARMS	0.1MG¤	N70315 001 JUN 09, 1987
>ADD>	AB		0.2MG¤	N70316 001 JUN 09, 1987
>ADD>	AB		0.3MG¤	N70317 001 JUN 09, 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
AB	COLMED LABS	3.75MG¤		N71242 001
			JUN 23, 1987 :	MAY 20, 1987
AB		7.5MG¤		N71243 001
			JUN 23, 1987 :	MAY 20, 1987
AB		15MG¤		N71244 001
			JUN 23, 1987 :	MAY 20, 1987
	TRANXENE			
	∂ ABBOTT LABS	3.75MG		N17105 001
	∂	7.5MG		N17105 002
	∂	15MG		N17105 003

TABLET; ORAL

>ADD>	**CLORAZEPATE DIPOTASSIUM**			
>ADD> AB	ABLE LABS	3.75MG¤		N71780 001
>ADD>				JUN 26, 1987
>ADD> AB		7.5MG¤		N71781 001
>ADD>				JUN 26, 1987
>ADD> AB		15MG¤		N71782 001
>ADD>				JUN 26, 1987
>ADD> AB	AM THERPTCS	3.75MG¤		N71747 001
>ADD>			JUN 23, 1987 :	JUN 09, 1987
>ADD> AB		7.5MG¤		N71748 001
>ADD>			JUN 23, 1987 :	JUN 09, 1987
>ADD> AB		15MG¤		N71749 001
>ADD>			JUN 23, 1987 :	JUN 09, 1987
	TRANXENE			
>ADD> AB	ABBOTT LABS	3.75MG		N17105 006
>ADD> AB		7.5MG		N17105 007
>ADD> AB		15MG		N17105 008

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

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

CUPRIC SULFATE

INJECTABLE; INJECTION

	CUPRIC SULFATE		
	LYPHOMED	EQ 0.4MG COPPER/ML¤	N19350 001 MAY 05, 1987

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

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

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

>ADD>	**DESIPRAMINE HCL**			
>ADD> AB	VITARINE	25MG¤		N71601 001
>ADD>				JUN 05, 1987
>ADD> AB		50MG¤		N71588 001
>ADD>				JUN 05, 1987
	NORPRAMIN			
>ADD> AB	MERRELL DOW	25MG		N14399 001
>ADD> AB		50MG		N14399 003

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

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

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

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

DIAZEPAM

CONCENTRATE; ORAL
DIAZEPAM INTENSOL

	ROXANE LABS	5MG/ML¤	N71415 001	APR 03, 1987

SOLUTION; ORAL
DIAZEPAM

	ROXANE LABS	5MG/5ML¤	N70928 001	APR 03, 1987

TABLET; ORAL
DIAZEPAM

AB	COLMED LABS	2MG¤	N70903 001	APR 01, 1987
AB		5MG¤	N70904 001	APR 01, 1987
AB		10MG¤	N70905 001	APR 01, 1987
AB	DANBURY PHARMA	2MG¤	N71134 001	FEB 03, 1987
AB		5MG¤	N71135 001	FEB 03, 1987
AB		10MG¤	N71136 001	FEB 03, 1987

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
DICYCLOMINE HCL

> ADD >	AB	BARR LABS	10MG	N84505 001	OCT 21, 1986

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 HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	TRAVENOL LABS	80MG/100ML¤	N19615 001	MAR 27, 1987
AP		160MG/100ML¤	N19615 002	MAR 27, 1987
AP		320MG/100ML¤	N19615 003	MAR 27, 1987
		640MG/100ML¤	N19615 004	MAR 27, 1987

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL

AB	CHELSEA LABS	EQ 10MG BASE¤	N70952 001	MAR 04, 1987

· DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

	DOXEPIN HCL		
AB	CORD LABS	EQ 10MG BASE¤	N71487 001 MAR 02, 1987
AB		EQ 100MG BASE¤	N71562 001 MAR 02, 1987
AB	DANBURY PHARMA	EQ 10MG BASE¤	N71485 001 APR 30, 1987
AB		EQ 25MG BASE¤	N71486 001 APR 30, 1987
AB		EQ 50MG BASE¤	N71238 001 APR 30, 1987
AB		EQ 75MG BASE¤	N71326 001 APR 30, 1987
AB		EQ 100MG BASE¤	N71239 001 APR 30, 1987

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

	/ADRIAMYCIN/		
>DLT<	/FARMITALIA/	/10MG/VIAL/	/N50467/001/
>DLT<		/20MG/VIAL/	/N50467/003/
>DLT<			/MAY/20,/1985/
>DLT<		/50MG/VIAL/	/N50467/002/
>ADD<	ADRIAMYCIN RDF		
>ADD<	FARMITALIA	10MG/VIAL	N50467 001
>ADD<		20MG/VIAL	N50467 003 MAY 20, 1985
>ADD<		50MG/VIAL	N50467 002

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

	XYLOCAINE W/ EPINEPHRINE		
	ASTRA PHARM PRODS	0.005MG/ML;1%	N06488 018 NOV 13, 1986
		0.005MG/ML;2%	N06488 019 NOV 13, 1986

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

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

ESTRADIOL CYPIONATE

INJECTABLE; INJECTION

	ESTRADIOL CYPIONATE		
AO	QUAD PHARMS	5MG/ML¤	N89310 001 FEB 09, 1987

ESTROGENS, CONJUGATED

TABLET; ORAL

	CONJUGATED ESTROGENS		
>ADD< BS	∂ CHELSEA LABS	0.625MG	N85800 001
>ADD< BS	∂	1.25MG	N85801 001
>ADD< BS	∂	2.5MG	N85826 001
BS	∂ HEATHER DRUG	0.625MG	N83356 001
BS	∂	1.25MG	N83360 001
BS	∂	2.5MG	N84650 001
BS	∂ PRIVATE FMLTNS	0.625MG	N83354 003
BS	∂	1.25MG	N83592 001
BS	∂	2.5MG	N85908 001

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

ETIDRONATE DISODIUM

INJECTABLE; INJECTION

	DIDRONEL		
	NORWICH EATON	50MG/ML¤	N19545 001 APR 20, 1987

FAMOTIDINE

POWDER FOR RECONSTITUTION; ORAL
PEPCID
MS&D RES LABS 40MG/5ML¤ N19527 001
FEB 02, 1987

FLECAINIDE ACETATE

TABLET; ORAL
TAMBOCOR
∂ RIKER LABS 200MG N18830 002
OCT 31, 1985

FLUNISOLIDE

AEROSOL, METERED; INHALATION
AEROBID
> DLT > /KEY/PHARMS/ /0.025MG/INH/ /N18340/001/
> DLT > /AUG/17,/1984/
> ADD > KEY PHARMS 0.25MG/INH N18340 001
> ADD > AUG 17, 1984

FLUOCINONIDE

CREAM; TOPICAL
> ADD > FLUOCINONIDE
> ADD > AB THAMES PHARMA 0.05%¤ N71500 001
> ADD > JUN 10, 1987

FLUOROMETHOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC
FLAREX
ALCON LABS 0.1% N19079 001
FEB 11, 1986

/OMNITROL/
/ALCON/LABS/ /0.1%/ /N19079/001/
/FEB/11,/1986/

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
AP LYPHOMED 50MG/ML¤ N89428 001
JAN 12, 1987
AP 50MG/ML¤ N89519 001
MAR 12, 1987

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
AP QUAD PHARMS 50MG/ML¤ N89368 001
FEB 03, 1987
AP 50MG/ML¤ N89455 001
FEB 03, 1987
AP SOLOPAK LABS 50MG/ML¤ N89434 001
MAR 26, 1987

FLUPHENAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
FLUPHENAZINE HCL
AP LYPHOMED 2.5MG/ML¤ N89556 001
APR 16, 1987

PROLIXIN
AP SQUIBB 2.5MG/ML N11751 005

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE
AP CARTER GLOGAU 10MG/ML¤ N70604 001
JAN 02, 1987

SOLUTION; ORAL
FUROSEMIDE
AA ROXANE LABS 10MG/ML¤ N70434 001
APR 22, 1987
40MG/5ML¤ N70433 001
APR 22, 1987

LASIX
AA HOECHST 10MG/ML N17688 001

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

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

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN

>ADD> AT	STERIS LABS	0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML¤	N62788 001	JUN 11, 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
AB	DANBURY PHARMA	0.5MG¤	N70981 001	MAR 06, 1987
AB		1MG¤	N70982 001	MAR 06, 1987
AB		2MG¤	N70983 001	MAR 06, 1987
AB		5MG¤	N70984 001	MAR 06, 1987
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

HALOPERIDOL

TABLET; ORAL
HALOPERIDOL

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
AB		10MG¤	N71132 001	MAY 12, 1987
AB		20MG¤	N71133 001	MAY 12, 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 02, 1987

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM PRESERVATIVE FREE

AP	WINTHROP BREON	10,000 UNITS/ML¤	N89522 001	MAY 04, 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; LABETALOL HYDROCHLORIDE

TABLET; ORAL

NORMOZIDE

AB	SCHERING	25MG;100MG¤	N19046 001	APR 06, 1987
AB		25MG;200MG¤	N19046 002	APR 06, 1987
AB		25MG;300MG¤	N19046 003	APR 06, 1987
AB		25MG;400MG¤	N19046 004	APR 06, 1987

TRANDATE-HCT

AB	GLAXO	25MG;100MG¤	N19174 001	APR 10, 1987
AB		25MG;200MG¤	N19174 002	APR 10, 1987
AB		25MG;300MG¤	N19174 003	APR 10, 1987
AB		25MG;400MG¤	N19174 004	APR 10, 1987

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	INVAMED	15MG;250MG¤	N70829 001	MAR 09, 1987
AB		25MG;250MG¤	N70830 001	MAR 09, 1987
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

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

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

AB	MYLAN PHARMS	25MG;40MG¤	N70946 001	MAR 04, 1987
AB		25MG;80MG¤	N70947 001	APR 01, 1987

HYDROCORTISONE

OINTMENT; TOPICAL

HYDROCORTISONE

AT	PHARMADERM	1%¤	N88842 001	FEB 09, 1987

HYDROCORTISONE BUTYRATE

SOLUTION; TOPICAL

LOCOID

	GIST BROCADES	0.1%¤	N19116 001 FEB 25, 1987

HYDROCORTISONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

HYDROCORTISONE SODIUM PHOSPHATE

AP	QUAD PHARMS	EQ 50MG BASE/ML¤	N89581 001	MAY 28, 1987

HYDROCORTONE

AP	MS&D	EQ 50MG BASE/ML	N12052 001

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
AB	HALSEY DRUG	300MG¤	N71028 001	MAR 23, 1987
AB		400MG¤	N71029 001	MAR 23, 1987
AB		600MG¤	N71030 001	MAR 23, 1987
> ADD > AB	SIDMAK LABS	400MG¤	N71666 001	JUN 18, 1987
> ADD > AB		600MG¤	N71667 001	JUN 18, 1987
> ADD > AB		800MG¤	N71668 001	JUN 18, 1987

IFEN

AB	LUCHEM PHARMS	800MG¤	N71769 001	MAY 08, 1987

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

AB	CHELSEA LABS	50MG¤	N71635 001	MAY 18, 1987
AB	CORD LABS	25MG¤	N70673 001	APR 29, 1987
AB		50MG¤	N70674 001	APR 29, 1987
> ADD > AB	HALSEY DRUG	25MG¤	N70782 001	JUN 03, 1987
> ADD > AB		50MG¤	N70635 001	JUN 03, 1987
AB	MUTUAL PHARM	25MG¤	N70899 001	FEB 09, 1987
AB		50MG¤	N70900 001	FEB 09, 1987

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

AB	SIDMAK LABS	25MG¤	N71148 001	MAR 18, 1987
AB		50MG¤	N71149 001	MAR 18, 1987

SUSPENSION; ORAL
INDOCIN

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

INDOMETHACIN

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

IRON DEXTRAN COMPLEX

INJECTABLE; INJECTION
IMFERON

AP	FISONS	EQ 50MG IRON/ML	N10787 002	
/AP/	/MERRELL DOW/	/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
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

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

KANAMYCIN SULFATE

INJECTABLE; INJECTION
KANAMYCIN SULFATE

AP	PHARMAFAIR	EQ 75MG BASE/2ML¤	N62668 001 MAY 07, 1987
AP		EQ 500MG BASE/2ML¤	N62672 001 MAY 07, 1987
AP		EQ 1GM BASE/3ML¤	N62669 001 MAY 07, 1987

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

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

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

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

AB	BOLAR PHARM	300MG¤	N70407 001 MAR 19, 1987
> ADD >	ROXANE LABS	150MG	N17812 002 JAN 28, 1987
> ADD >		600MG	N17812 003 JAN 28, 1987

LORAZEPAM

TABLET; ORAL
LORAZEPAM

AB	PUREPAC PHARM	0.5MG¤	N71403 001 APR 21, 1987
AB		1MG¤	N71404 001 APR 21, 1987
AB		2MG¤	N71141 001 APR 21, 1987
AB	SUPERPHARM	0.5MG¤	N71245 001 FEB 09, 1987
AB		1MG¤	N71246 001 FEB 09, 1987
AB		2MG¤	N71247 001 FEB 09, 1987
AB	WATSON LABS	0.5MG¤	N71086 001 MAR 23, 1987
AB		1MG¤	N71087 001 MAR 23, 1987
AB		2MG¤	N71088 001 MAR 23, 1987

MANGANESE SULFATE

INJECTABLE; INJECTION
MANGANESE SULFATE

	LYPHOMED	EQ 0.1MG MANGANESE/ML¤	N19228 001 MAY 05, 1987

MANNITOL

INJECTABLE; INJECTION
MANNITOL 10% IN PLASTIC CONTAINER

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

MANNITOL 25%

AP	ASTRA PHARM PRODS	12.5GM/50ML¤	N89239 001 MAY 06, 1987
AP		12.5GM/50ML¤	N89240 001 MAY 06, 1987

MANNITOL 5% IN PLASTIC CONTAINER

AP	ABBOTT LABS	5GM/100ML¤	N19603 001 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	
AB	DANBURY PHARMA	EQ 50MG BASE¤	N71468 001 APR 15, 1987	> ADD >
AB		EQ 100MG BASE¤	N71469 001 APR 15, 1987	> ADD >

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

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

METHOTREXATE SODIUM

INJECTABLE; INJECTION
ABITREXATE

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

METHOXSALEN

CAPSULE; ORAL
METHOXSALEN

BP	@ CORD LABS	10MG	N87781 001 JUN 08, 1982	

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	ABBOTT LABS	50MG/ML¤	N70698 001 JUN 15, 1987	> ADD >
AP		50MG/ML¤	N70699 001 JUN 15, 1987	> ADD >
AP	DUPONT CRI CARE	50MG/ML¤	N70691 001 JUN 19, 1987	> ADD >
AP		50MG/ML¤	N70849 001 JUN 19, 1987	> ADD >
AP	SOLOPAK LABS	50MG/ML¤	N70841 001 JAN 02, 1987	

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

AP	SOLOPAK LABS	EQ 10MG BASE/2ML¤	N70622 001 MAR 02, 1987	
AP		EQ 10MG BASE/2ML¤	N70623 001 MAR 02, 1987	
	REGLAN			
	ROBINS	EQ 10MG BASE/ML¤	N17862 004 MAY 28, 1987	> ADD >

SYRUP; ORAL
METOCLOPRAMIDE HCL

AA	MY K LABS	EQ 5MG BASE/5ML¤	N70949 001 MAR 06, 1987	
	REGLAN			
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
AB	BOLAR PHARM	EQ 10MG BASE¤	N70363 001 MAR 02, 1987
AB	INVAMED	EQ 10MG BASE¤	N70850 001 FEB 03, 1987

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

AB	MARTEC PHARMS	EQ 10MG BASE¤	N70598 001	FEB 02, 1987
> ADD > AB	SUPERPHARM	EQ 10MG BASE¤	N70926 001	JUN 26, 1987
> ADD > AB	WATSON LABS	EQ 10MG BASE¤	N70645 001	MAY 11, 1987

REGLAN

	ROBINS	EQ 5MG BASE¤	N17854 002	MAY 05, 1987

METRIZAMIDE

INJECTABLE; INJECTION
AMIPAQUE

NINTHROP BREON	2.5GM/VIAL	N17982 003	SEP 12, 1983
	13.5GM/VIAL	N17982 004	SEP 12, 1983

METRONIDAZOLE

TABLET; ORAL
SATRIC

> ADD > AB	SAVAGE LABS	500MG¤	N70731 001	JUN 08, 1987

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

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
VERSED

ROCHE	EQ 1MG BASE/ML¤	N18654 002	MAY 26, 1987

MINOXIDIL

TABLET; ORAL
LONITEN

AB	UPJOHN	2.5MG	N18154 001	
AB		10MG	N18154 003	

MINODYL

AB	QUANTUM PHARMCS	10MG¤	N71534 001	MAR 19, 1987

MINOXIDIL

AB	DANBURY PHARMA	2.5MG¤	N71344 001	MAR 03, 1987
AB		10MG¤	N71345 001	MAR 03, 1987

MOMETASONE FUROATE

CREAM; TOPICAL
ELOCON

	SCHERING	0.1%¤	N19625 001	MAY 06, 1987

OINTMENT; TOPICAL
ELOCON

	SCHERING	0.1%¤	N19543 001	APR 30, 1987

MORPHINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL
MS CONTIN

	PURDUE FRDRK	30MG¤	N19516 001	MAY 29, 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

NAPROXEN

SUSPENSION; ORAL
NAPROSYN
SYNTEX LABS 25MG/ML¤ N18965 001
MAR 23, 1987

NITROGLYCERIN

INJECTABLE; INJECTION
NITROGLYCERIN
AP LYPHOMED 5MG/ML¤ N71203 001
MAY 08, 1987

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

PASTILLE; ORAL
MYCOSTATIN
SQUIBB 200,000 UNITS¤ N50619 001
APR 09, 1987

SUSPENSION; ORAL
NYSTATIN
>ADD> AA BIOCRAFT LABS 100,000 UNITS/ML¤ N62670 001
>ADD> JUN 18, 1987

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN-TRIAMCINOLONE ACETONIDE
AT THAMES PHARMA 100,000 UNITS/GM;0.1%¤ N62347 001
MAR 30, 1987

OINTMENT; TOPICAL
MYKACET
AT NMC LABS 100,000 UNITS/GM;0.1%¤ N62733 001
MAR 09, 1987

OXAZEPAM

TABLET; ORAL
OXAZEPAM
AB BARR LABS 15MG¤ N70683 001
JAN 16, 1987
AB DANBURY PHARMA 15MG¤ N71494 001
APR 21, 1987
AB PARKE DAVIS 15MG¤ N71508 001
FEB 02, 1987

SERAX
AB WYETH 15MG N15539 008

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PHERAZINE VC
AA HALSEY DRUG 5MG/5ML;6.25MG/5ML¤ N88868 001
MAR 02, 1987

PHENYTOIN SODIUM

INJECTABLE; INJECTION
PHENYTOIN SODIUM
AP ABBOTT LABS 50MG/ML¤ N89521 001
MAR 17, 1987

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL
COLYTE
>ADD> REED & CARNRICK 240GM/BOT;2.98GM/BOT;6.72GM/BOT;
>ADD> 5.84GM/BOT;22.72GM/BOT¤ N18983 007
>ADD> JUN 12, 1987

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

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

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

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
PREDNISOLONE SODIUM PHOSPHATE

AP	STERIS LABS /SOLU-PRED/ /STERIS/LABS/	EQ 20MG PHOSPHATE/ML /EQ 20MG PHOSPHATE/ML/	N80517 001 /N80517/001/	

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE

AT	ə BARNES HIND	EQ 0.9% PHOSPHATE	N84168 001	
AT	ə	EQ 0.9% PHOSPHATE	N84169 001	
AT	ə	EQ 0.9% PHOSPHATE	N84172 001	
AT	ə MAURRY BIO	EQ 0.9% PHOSPHATE	N83358 002	

PROCAINAMIDE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL
PROCAINAMIDE HCL

AB	BOLAR PHARM	1GM¤	N89520 001 JAN 15, 1987	
AB	COPLEY PHARM	750MG¤	N89438 001 MAR 23, 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

CAPSULE, CONTROLLED RELEASE; ORAL
INDERAL LA

	AYERST LABS	60MG¤	N18553 004 MAR 18, 1987	

CONCENTRATE; ORAL
PROPRANOLOL HCL INTENSOL

	ROXANE LABS	80MG/ML¤	N71388 001 MAY 15, 1987	

SOLUTION; ORAL
PROPRANOLOL HCL

	ROXANE LABS	20MG/5ML¤	N70979 001 MAY 15, 1987	
		40MG/5ML¤	N70690 001 MAY 15, 1987	

TABLET; ORAL
PROPRANOLOL HCL

AB	BOLAR PHARM	10MG¤	N70378 001 MAR 19, 1997	
AB		20MG¤	N70379 001 MAR 19, 1987	
AB		40MG¤	N70380 001 MAR 19, 1987	
AB		60MG¤	N70381 001 MAR 19, 1987	
AB		80MG¤	N70382 001 MAR 19, 1987	
AB	CHELSEA LABS	60MG¤	N70143 001 JAN 15, 1987	
AB	INTERPHARM	10MG¤	N71368 001 MAY 05, 1987	
AB		20MG¤	N71369 001 MAY 05, 1987	
AB		40MG¤	N71370 001 MAY 05, 1987	
AB		80MG¤	N71371 001 MAY 05, 1987	

PROTAMINE SULFATE

INJECTABLE; INJECTION
PROTAMINE SULFATE

AP	LYPHOMED	10MG/ML¤	N89454 001 APR 07, 1987	

QUAZEPAM

TABLET; ORAL
DORMALIN
SCHERING 7.5MG¤ N18708 003 FEB 26, 1987

QUINIDINE GLUCONATE

TABLET, CONTROLLED RELEASE; ORAL
QUINIDINE GLUCONATE
AB HALSEY DRUG 324MG¤ N89476 001 APR 10, 1987
AB MUTUAL PHARM 324MG¤ N89338 001 FEB 11, 1987

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER
LYPHOMED 234MG/ML¤ N19329 001 APR 22, 1987

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION
HUMATROPE
LILLY 5MG/VIAL¤ N19640 004 MAR 08, 1986

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
/AA/ /SUPERPHARM/ /25MG/ /N89364/001/ /NOV/07,/1986/
AB SUPERPHARM 25MG N89364 001 NOV 07, 1986

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULFACETAMIDE SODIUM
AT STERIS LABS 30%¤ N89068 001 MAY 05, 1987

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AP ELKINS SINN 80MG/ML;16MG/ML¤ N70627 001 DEC 29, 1987 : APR 30, 1987
AP 80MG/ML;16MG/ML¤ N70628 001 DEC 29, 1987 : APR 30, 1987
AP LYPHOMED 80MG/ML;16MG/ML¤ N70223 001 DEC 29, 1987 : JAN 16, 1987

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

SUPROFEN

CAPSULE; ORAL
SUPROL
@ MCNEIL PHARM 200MG N18217 001 DEC 24, 1985

TAMOXIFEN CITRATE

TABLET; ORAL

	NOLVADEX			
AB	STUART PHARMS	EQ 10MG BASE	N17970 001	
	TAMOXIFEN CITRATE			
AB	BARR LABS	EQ 10MG BASE¤	N70929 001	
		AUG 20, 2002 :	APR 01, 1987	

TECHNETIUM TC-99M MEBROFENIN KIT

INJECTABLE; INJECTION

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

TECHNETIUM TC-99M PYROPHOSPHATE KIT

INJECTABLE; INJECTION

>ADD>	**AN-PYROTEC**			
>ADD> AP	CIS US	N/A¤	N19039 001	
>ADD>			JUN 30, 1987	

TEMAZEPAM

CAPSULE; ORAL

	TEMAZEPAM			
AB	BOLAR PHARM	15MG¤	N70383 001	
			MAR 23, 1987	
AB		30MG¤	N70384 001	
			MAR 23, 1987	
AB	PAR PHARM	15MG¤	N71456 001	
			APR 21, 1987	
AB		30MG¤	N71457 001	
			APR 21, 1987	

THEOPHYLLINE

TABLET, CONTROLLED RELEASE; ORAL

	DURAPHYL			
AB	FOREST LABS	300MG †	N88505 001	
			APR 03, 1985	
BC		100MG	N88503 001	
			APR 03, 1985	
BC		200MG	N88504 001	
			APR 03, 1985	

THEOPHYLLINE

TABLET, CONTROLLED RELEASE; ORAL

	THEOPHYLLINE			
/AB/	/FOREST LABS/	/300MG/ †	/N88505/001/	
			/APR 03, 1985/	
/BC/		/100MG/	/N88503/001/	
			/APR 03, 1985/	
/BC/		/200MG/	/N88504/001/	
			/APR 03, 1985/	

THIOTHIXENE

CAPSULE; ORAL

	HAVANE			
>ADD> AB	ROERIG	1MG	N16584 001	
>ADD> AB		2MG	N16584 002	
>ADD> AB		5MG	N16584 003	
>ADD> AB		10MG	N16584 004	
>ADD>	**THIOTHIXENE**			
>ADD> AB	CHELSEA LABS	2MG¤	N71626 001	
>ADD>			JUN 25, 1987	
>ADD> AB		5MG¤	N71627 001	
>ADD>			JUN 25, 1987	
>ADD> AB		10MG¤	N71628 001	
>ADD>			JUN 25, 1987	
>ADD> AB	CORD LABS	1MG¤	N71610 001	
>ADD>			JUN 24, 1987	
>ADD> AB		2MG¤	N71570 001	
>ADD>			JUN 24, 1987	
>ADD> AB		5MG¤	N71529 001	
>ADD>			JUN 24, 1987	
>ADD> AB		10MG¤	N71530 001	
>ADD>			JUN 24, 1987	
>ADD> AB	DANBURY PHARMA	1MG¤	N70600 001	
>ADD>			JUN 05, 1987	
>ADD> AB		2MG¤	N70601 001	
>ADD>			JUN 05, 1987	
>ADD> AB		5MG¤	N70602 001	
>ADD>			JUN 05, 1987	
>ADD> AB		10MG¤	N70603 001	
>ADD>			JUN 05, 1987	
>ADD> AB	MYLAN PHARMS	1MG¤	N71090 001	
>ADD>			JUN 23, 1987	
>ADD> AB		2MG¤	N71091 001	
>ADD>			JUN 23, 1987	
>ADD> AB		5MG¤	N71092 001	
>ADD>			JUN 23, 1987	
>ADD> AB		10MG¤	N71093 001	
>ADD>			JUN 23, 1987	

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

NAVANE

> ADD >	AA	ROERIG	EQ 5MG BASE/ML	N16758 001

THIOTHIXENE HCL

> ADD >	AA	LEMMON	EQ 5MG BASE/ML¤	N71184 001 JUN 22, 1987

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

NEBCIN

	LILLY	EQ 10MG BASE/ML¤	N62707 001 APR 29, 1987

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

AB	BOLAR PHARM	250MG¤	N89110 001 MAY 29, 1987
AB		500MG¤	N89111 001 MAY 29, 1987

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL

AB	BARR LABS	50MG¤	N71258 001 MAR 25, 1987
AB		100MG¤	N71196 001 MAR 25, 1987
AB	COLMED LABS	50MG¤	N70491 001 APR 29, 1987
AB		100MG¤	N70492 001 APR 29, 1987

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HCL

AP	WINTHROP BREON	100MG/ML¤	N88804 001 APR 03, 1987

TRIMETHOPRIM

TABLET; ORAL

TRIMETHOPRIM

> ADD >	AB	BIOCRAFT LABS	200MG¤	N71259 001 JUN 18, 1987

VALPROIC ACID

CAPSULE; ORAL

VALPROIC ACID

> ADD >	AB	FORMUTEC	250MG¤	N70631 001 JUN 11, 1987

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

LYPHOCIN

AP	LYPHOMED	EQ 500MG BASE/VIAL¤	N62663 001 MAR 17, 1987

VANCOCIN HCL

AP	LILLY	EQ 500MG BASE/VIAL¤	N62716 001 MAR 13, 1987
		EQ 1GM BASE/VIAL¤	N62716 002 MAR 13, 1987

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

VERAPAMIL HCL

AP	ABBOTT LABS	2.5MG/ML¤	N70737 001 MAY 06, 1987
AP		2.5MG/ML¤	N70738 001 MAY 06, 1987
AP		2.5MG/ML¤	N70739 001 MAY 06, 1987
AP		2.5MG/ML¤	N70740 001 MAY 06, 1987
AP	WINTHROP BREON	2.5MG/ML¤	N70577 001 FEB 02, 1987

VINBLASTINE SULFATE

INJECTABLE; INJECTION

VINBLASTINE SULFATE

AP	BEN VENUE LABS	10MG/VIAL¤	N89395 001 APR 09, 1987
AP	LYPHOMED	1MG/ML¤	N89515 001 APR 29, 1987

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

AP	QUAD PHARMS	1MG/ML¤	N89311 001 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
XYLO-PFAN

AA	ADRIA LABS	25GM/BOT	N17605 001	

XYLOSE

AA	LYNE LABS	25GM/BOT¤	N18856 001 MAR 26, 1987	

ZIDOVUDINE

CAPSULE; ORAL
RETROVIR

	BURROUGHS WELLC	100MG¤	N19655 001 MAR 19, 1987	

ZINC SULFATE

INJECTABLE; INJECTION
ZINC SULFATE

	LYPHOMED	EQ 1MG ZINC/ML¤		N19229 002 MAY 05, 1987

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN

ROXANE LABS	120MG¤	N71010 001 MAY 12, 1987
	650MG¤	N71011 001 MAY 12, 1987
SUPPOSITORIA	120MG¤	N70607 001 APR 06, 1987
UPSHER SMITH	325MG¤	N18337 002

ACETAMINOPHEN; DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL
DRIXORAL PLUS

SCHERING	500MG;3MG;60MG¤	N19453 001 MAY 22, 1987

ASPIRIN

TABLET, CONTROLLED RELEASE; ORAL
MEASURIN

WINTHROP BREON	650MG¤	N16030 002

8-HOUR BAYER

WINTHROP BREON	650MG¤	N16030 001

BACITRACIN

OINTMENT; TOPICAL
BACITRACIN

COMBE	500 UNITS/GM¤	N62799 001 MAY 14, 1987

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
CHLORHEXIDINE GLUCONATE

KENDALL	4%¤	N19490 001 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
ANTITUSSIVE

PERRIGO	12.5MG/5ML¤	N71292 001 APR 10, 1987

VICKS FORMULA 44

VICKS HLTH CARE	12.5MG/5ML¤	N70524 001 JAN 14, 1987

IBUPROFEN

TABLET; ORAL
ACHES-N-PAIN

LEDERLE LABS	200MG¤	N71065 001 MAY 28, 1987

IBUPROFEN

INTERPHARM	200MG¤	N71333 001 FEB 17, 1987
MUTUAL PHARM	200MG¤	N71229 001 APR 01, 1987
PAR PHARM	200MG¤	N71575 001 MAY 08, 1987
PUREPAC PHARM	200MG¤	N71664 001 FEB 03, 1987

NEUVIL

LUCHEM PHARMS	200MG¤	N71144 001 JAN 20, 1987

TRENDAR

WHITEHALL LABS	200MG	N18989 002 JUL 10, 1986

> ADD > INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN

> ADD > INJECTABLE; INJECTION
> ADD > HUMULIN U

> ADD > LILLY	40 UNITS/ML¤	N19571 001 JUN 10, 1987
> ADD >	100 UNITS/ML¤	N19571 002 JUN 10, 1987

POVIDONE-IODINE

SPONGE; TOPICAL
E-Z SCRUB 241

DESERET MED	10%¤	N19476 001 JAN 07, 1987

> ADD > PSEUDOEPHEDRINE POLISTIREX

> ADD > SUSPENSION, CONTROLLED RELEASE; ORAL
> ADD > PSEUDO-12
> ADD > PENNWALT EQ 60MG HCL/5ML N19401 001
> ADD > JUN 19, 1987

SODIUM MONOFLUOROPHOSPHATE

> ADD > PASTE; DENTAL
> ADD > EXTRA-STRENGTH AIM
> ADD > LEVER BROTHERS 1.2% N19518 001
> ADD > JUN 03, 1987

PENTASTARCH 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
PENTASPAN(R)
DUPONT CRI CARE 10G/100ML;0.9G/100ML N 841207
MAY 19, 1987

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.

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

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
ETIDRONATE DISODIUM 50MG/ML	DIDRONEL I.V. INJECTABLE; INJECTION	NORWICH EATON	19545 001 APR 24, 1987	ODE APR 24, 1994
PENTASTARCH 10% IN SODIUM CHLORIDE 0.9% 10GM/100ML;0.9GM/100ML	PENTASPAN INJECTABLE; INJECTION	DUPONT CRI CARE	841207 001 MAY 19, 1987	ODE MAY 19, 1994
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 JUNE 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
ALBUTEROL (TABLET)	MAY 05, 1987	
CEPHALEXIN (TABLET AND CAPSULE)	AUG 13, 1986	MAR 19, 1987
CLORAZEPATE DIPOTASSIUM	MAR 10, 1986	FEB 17, 1987
DESIPRAMINE HYDROCHLORIDE (TABLET)	APR 28, 1987	
DISSOLUTION TESTING (GENERAL)	APR 01, 1978*	
HALOPERIDOL (TABLET)	APR 30, 1987	
LEUCOVORIN CALCIUM (TABLET)	APR 28, 1987	
POTASSIUM CHLORIDE (SLOW-RELEASE; TABLET AND CAPSULE)	JAN 17, 1987	

* 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	325MG 2.5MG	87 P-0129/CP	MIKART	NEW STRENGTH	APPROVED JUN 08, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 5MG	87 P-0129/CP	MIKART	NEW STRENGTH	APPROVED JUN 08, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 7.5MG	87 P-0129/CP	MIKART	NEW STRENGTH	APPROVED JUN 08, 1987

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 10MG	87 P-0129/CP	MIKART	NEW STRENGTH	APPROVED JUN 08, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE SOLUTION; ORAL	325MG/15ML 2.5MG/15ML	87 P-0129/ CP02	MIKART	NEW STRENGTH	APPROVED JUN 08, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE SOLUTION; ORAL	325MG/15ML 5MG/15ML	87 P-0129/ CP02	MIKART	NEW STRENGTH	APPROVED JUN 08, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE SOLUTION; ORAL	325MG/15ML 7.5MG/15ML	87 P-0129/ CP02	MIKART	NEW STRENGTH	APPROVED JUN 08, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE SOLUTION; ORAL	325MG/15ML 10MG/15ML	87 P-0129/ CP02	MIKART	NEW STRENGTH	APPROVED JUN 08, 1987

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; HYDROCODONE BITARTRATE LIQUID; ORAL	500MG/15ML 7.5MG/15ML	85 P-0439/ CP0003	RUSS PHARMS	NEW STRENGTH	APPROVED APR 01, 1987
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

ANDA SUITABILITY PETITIONS

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
ASPIRIN; HYDROCODONE BITARTRATE TABLET; ORAL	500MG 7.5MG	87 P-0100/CP	KING AND SPAULDING	NEW STRENGTH	APPROVED APR 24, 1987
BRETYLIUM TOSYLATE INJECTABLE; INJECTION	200MG/ML (10ML/CONTAINER)	85 P-0546/CP	INTL MEDTN SYS	NEW STRENGTH	APPROVED JAN 20, 1987
BRETYLIUM TOSYLATE IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (50ML/CONTAINER)	87 P-0065/CP	LYPHOMED	NEW STRENGTH	APPROVED APR 27, 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
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE TABLET, CONTROLLED RELEASE; ORAL	12MG 120MG	87 P-0165/CP	SANDOZ CONSUMER	NEW DOSAGE FORM	APPROVED MAY 19, 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
CYTARABINE INJECTABLE; INJECTION	1000MG/VIAL	86 P-0313/CP	QUAD PHARMS	NEW STRENGTH	APPROVED MAY 07, 1987
CYTARABINE INJECTABLE; INJECTION	20MG/ML (50ML CONTAINER)	86 P-0428/ CP0002	ADRIA LABS	NEW STRENGTH	APPROVED MAY 07, 1987
DEXTROMETHORPHAN POLISTIREX SUSPENSION, CONTROLLED RELEASE; ORAL	EQ 15MG HBR/5ML	87 P-0088/CP	KING AND SPAULDING	NEW STRENGTH	APPROVED APR 27, 1987

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
DIAZOXIDE INJECTABLE; INJECTION	15MG/ML (10ML/CONTAINER)	87 P-0061/CP	LYPHOMED	NEW STRENGTH	APPROVED APR 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
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 LABS	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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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
PROMETHAZINE HYDROCHLORIDE INJECTABLE; INJECTION	25MG/ML (2ML/VIAL)	87 P-0087/ CP00002	LYPHOMED	NEW STRENGTH	APPROVED MAY 01, 1987
PROMETHAZINE HYDROCHLORIDE INJECTABLE; INJECTION	50MG/ML (2ML/VIAL)	87 P-0087/CP	LYPHOMED	NEW STRENGTH	APPROVED MAY 01, 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
VINBLASTINE SULFATE INJECTABLE; INJECTION	1MG/ML (25ML/VIAL)	87 P-0112/CP	QUAD PHARMS	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUN 08, 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
ASPIRIN; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	224MG 32MG 5MG	86 P-0243/CP	MASON PHARMS INC	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	DENIED JUN 12, 1987
ASPIRIN; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 30MG 5MG	85 P-0455/CP	CENTRAL PHARM	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	DENIED JUN 08, 1987
ASPIRIN; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	356.4MG 30MG 5MG	86 P-0243/ CP002	MASON PHARMS INC	NEW COMBINATION NEW DOSAGE FORM	DENIED JUN 16, 1987
HYDROCORTISONE; SALICYLIC ACID; SULFUR CREAM; TOPICAL	0.25% 2.35% 4%	86 P-0439/CP	C&M PHARMA	NEW COMBINATION NEW INGREDIENT	DENIED MAY 06, 1987

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
PROCAINAMIDE HYDROCHLORIDE TABLET; ORAL	500MG 750MG 1000MG	85 P-0181/CP	FOREST LABS	NEW DOSAGE FORM	DENIED APR 21, 1987
PROCAINAMIDE HYDROCHLORIDE TABLET, CONTROLLED RELEASE; ORAL	500MG 750MG 1000MG	86 P-0328/CP	KV PHARM	NEW DOSAGE FORM	DENIED APR 21, 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
I-63	BIOPSY PROVEN MINIMAL CHANGE NEPHROTIC SYNDROME IN CHILDREN
I-64	LONG-TERM TREATMENT OF ANGINA PECTORIS
I-65	ADULT INTRAVENOUS CONTRAST ENHANCED COMPUTED TOMOGRAPHY OF THE HEAD AND BODY
I-66	PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING
I-67	PREVENTION OF POSTOPERATIVE DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM IN TOTAL HIP REPLACEMENT SURGERY

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
U-17	METHOD FOR TREATMENT OF HERPETIC INFECTIONS

	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
>ADD>	19621 001	VENTOLIN; ALBUTEROL SULFATE	3705233	DEC 05, 1989			
>ADD>			3644353	FEB 22, 1989			
	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
	18057 001	PLATINOL; CISPLATIN	4177263	DEC 04, 1996			
	18057 002	PLATINOL; CISPLATIN	4177263	DEC 04, 1996			
	18057 003	PLATINOL-AQ; CISPLATIN	4177263	DEC 04, 1996			
	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
	12141 001	CYTOXAN; CYCLOPHOSPHAMIDE				I-63	APR 29, 1990
	12141 002	CYTOXAN; CYCLOPHOSPHAMIDE				I-63	APR 29, 1990
	12142 001	CYTOXAN; CYCLOPHOSPHAMIDE				I-63	APR 29, 1990
	12142 002	CYTOXAN; CYCLOPHOSPHAMIDE				I-63	APR 29, 1990
	12142 003	CYTOXAN; CYCLOPHOSPHAMIDE				I-63	APR 29, 1990
	12142 004	CYTOXAN; CYCLOPHOSPHAMIDE				I-63	APR 29, 1990
	12142 005	CYTOXAN; CYCLOPHOSPHAMIDE				I-63	APR 29, 1990
	12142 006	LYOPHILIZED CYTOXAN; CYCLOPHOSPHAMIDE	4537883	AUG 27, 2002		I-63	APR 29, 1990
	12142 007	LYOPHILIZED CYTOXAN; CYCLOPHOSPHAMIDE	4537883	AUG 27, 2002		I-63	APR 29, 1990
	12142 008	LYOPHILIZED CYTOXAN; CYCLOPHOSPHAMIDE	4537883	AUG 27, 2002		I-63	APR 29, 1990
	12142 009	LYOPHILIZED CYTOXAN; CYCLOPHOSPHAMIDE	4537883	AUG 27, 2002		I-63	APR 29, 1990
	12142 010	LYOPHILIZED CYTOXAN; CYCLOPHOSPHAMIDE	4537883	AUG 27, 2002		I-63	APR 29, 1990
>ADD>	18885 002	EMBOLEX; DIHYDROERGOTAMINE MESYLATE	4402949	SEP 06, 2000		I-67	JUN 22, 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		

APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
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		
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		
19545 001	DIDRONEL; ETIDRONATE DISODIUM	4254114	MAR 03, 1998			
		4216211	AUG 05, 1997			
		4137309	JAN 30, 1996		ODE	APR 20, 1994
		3683080	AUG 08, 1989		NDF	APR 20, 1990
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			
19415 002	METRODIN; FLUMAZENIL				NE	SEP 18, 1989
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		

	APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	18587 001	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5	NCE	SEP 07, 1992
	18587 002	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5	NCE	SEP 07, 1992
	18587 003	WYTENSIN; GUANABENZ ACETATE	3658993	APR 25, 1989	U-5	NCE	SEP 07, 1992
	19046 001	NORMOZIDE; HYDROCHLOROTHIAZIDE	4066755	JAN 03, 1995			
			4012444	MAR 15, 1994		NC	APR 06, 1990
	19046 002	NORMOZIDE; HYDROCHLOROTHIAZIDE	4066755	JAN 03, 1995			
			4012444	MAR 15, 1994		NC	APR 06, 1990
	19046 003	NORMOZIDE; HYDROCHLOROTHIAZIDE	4066755	JAN 03, 1995			
			4012444	MAR 15, 1994		NC	APR 06, 1990
	19046 004	NORMOZIDE; HYDROCHLOROTHIAZIDE	4066755	JAN 03, 1995			
			4012444	MAR 15, 1994		NC	APR 06, 1990
	19174 001	TRANDATE-HCT; HYDROCHLOROTHIAZIDE	4066755	JAN 03, 1995			
			4012444	MAR 15, 1994		NC	APR 10, 1990
	19174 002	TRANDATE-HCT; HYDROCHLOROTHIAZIDE	4066755	JAN 03, 1995			
			4012444	MAR 15, 1994		NC	APR 10, 1990
	19174 003	TRANDATE-HCT; HYDROCHLOROTHIAZIDE	4066755	JAN 03, 1995			
			4012444	MAR 15, 1994		NC	APR 10, 1990
	19174 004	TRANDATE-HCT; HYDROCHLOROTHIAZIDE	4066755	JAN 03, 1995			
			4012444	MAR 15, 1994		NC	APR 10, 1990
						NP	JUN 10, 1990
>ADD>	19571 001	HUMULIN U; INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN				NP	JUN 10, 1990
>ADD>	19571 002	HUMULIN U; INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN					
	18956 001	OMNIPAQUE 180; IOHEXOL	4396597	JUL 14, 1998		I-65	MAY 12, 1990
			4250113	DEC 26, 1999		NCE	DEC 26, 1990
	18956 002	OMNIPAQUE 240; IOHEXOL	4396597	JUL 14, 1998		I-65	MAY 12, 1990
			4250113	DEC 26, 1999		NCE	DEC 26, 1990
	18956 003	OMNIPAQUE 300; IOHEXOL	4396597	JUL 14, 1998		I-65	MAY 12, 1990
			4250113	DEC 26, 1999		NCE	DEC 26, 1990
	18956 004	OMNIPAQUE 350; IOHEXOL	4396597	JUL 14, 1998		I-65	MAY 12, 1990
			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		
	18029 001	RITALIN-SR; METHYLPHENIDATE HYDROCHLORIDE	4137300	JAN 30, 1996		NCE	APR 30, 1992
	17862 001	REGLAN; METOCLOPRAMIDE HYDROCHLORIDE	4536386	AUG 20, 2002	U-13		
>ADD>	17862 004	REGLAN; METOCLOPRAMIDE HYDROCHLORIDE	4536386	AUG 20, 2002	U-13	I-66	MAY 28, 1990
>ADD>						NS	MAY 28, 1990
	17963 001	LOPRESSOR; METOPROLOL TARTRATE	3998790	DEC 21, 1993		I-64	JUN 27, 1989
	17963 002	LOPRESSOR; METOPROLOL TARTRATE	3998790	DEC 21, 1993		I-64	JUN 27, 1989
	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
	18654 002	VERSED; MIDAZOLAM HYDROCHLORIDE	4280957	JUL 28, 1998		NCE	DEC 20, 1990
	19543 001	ELOCON; MOMETASONE FUROATE	4472393	SEP 18, 2001		NCE	APR 30, 1992
	19625 001	ELOCON; MOMETASONE FUROATE	4472393	SEP 18, 2001		NCE	APR 30, 1992
	19516 001	MS CONTIN; MORPHINE SULFATE				NDF	MAY 29, 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
	17581 002	NAPROSYN; NAPROXEN	3998966	DEC 21, 1993		I-62	MAR 23, 1990
			3904682	SEP 09, 1992		D-13	MAR 23, 1990
	17581 003	NAPROSYN; NAPROXEN	3998966	DEC 21, 1993		I-62	MAR 23, 1990
			3904682	SEP 09, 1992		D-13	MAR 23, 1990
	17581 004	NAPROSYN; NAPROXEN	3998966	DEC 21, 1993		I-62	MAR 23, 1990
			3904682	SEP 09, 1992		D-13	MAR 23, 1990
	18965 001	NAPROSYN; NAPROXEN	4009197	SEP 09, 1992			
			4001301	SEP 09, 1992			
			3998966	DEC 21, 1993			
			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		
	18553 004	INDERAL LA; PROPRANOLOL HYDROCHLORIDE	4138475	FEB 06, 1996			
	19536 001	INDERAL; PROPRANOLOL HYDROCHLORIDE	4600708	JUL 15, 2003		D-7	OCT 31, 1989
	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
>ADD>	19518 001	EXTRA-STRENGTH AIM; SODIUM MONOFLUOROPHOSPHATE				NS	AUG 06, 1989
	19518 002	EXTRA-STRENGTH AIM; SODIUM MONOFLUOROPHOSPHATE				NS	AUG 06, 1989
	19107 001	PROTROPIN; SOMATREM	4658021	APR 14, 2004		NCE	OCT 17, 1990
	19640 004	HUMATROPE; SOMATROPIN, BIOSYNTHETIC				ODE	MAR 08, 1994

APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
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
18682 001	TROSYD; TIOCONAZOLE	4661493	APR 28, 2004	U-17		
19355 001	VAGISTAT; TIOCONAZOLE	4661493	APR 28, 2004	U-17		
14103 003	ONCOVIN; VINCRISTINE SULFATE	4619935	OCT 28, 2003			
19655 001	RETROVIR; ZIDOVUDINE				ODE	MAR 19, 1994
					NCE	MAR 19, 1992

DRUG PRODUCTS APPROVED UNDER SECTION 505 OF THE ACT
BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
PATENT AND EXCLUSIVITY DATA

APPL/PROD	TRADE NAME; INGREDIENT NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
83715 001	PROMIT; DEXTRAN 1 IN SODIUM CHLORIDE 0.6%	4201772	AUG 17, 1998		NCE	OCT 30, 1989
841207 001	PENTASPAN; PENTASTARCH 10% IN SODIUM CHLORIDE 0.9%				ODE	MAY 19, 1994