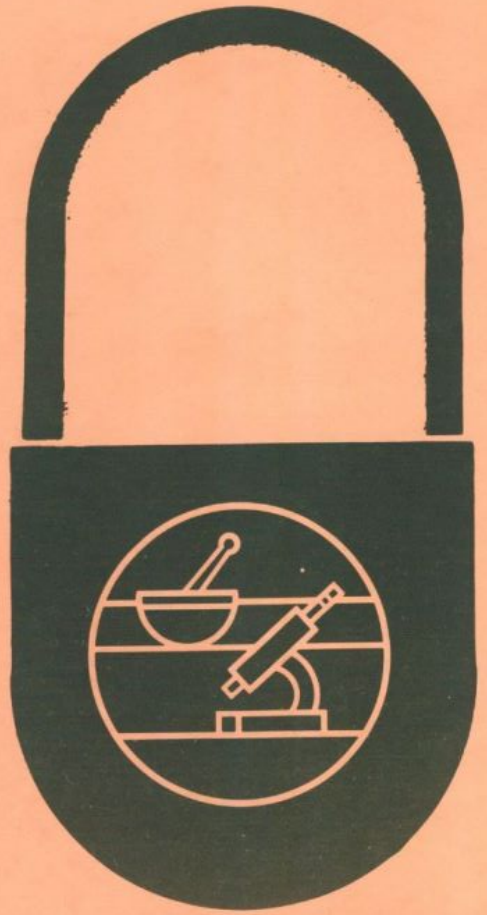
CUMULATIV
SUPPLEMENT 1
JAN'87-NOV'87



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 DRUG EVALUATION AND RESEARCH

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

7TH EDITION

CUMULATIVE SUPPLEMENT 11

NOVEMBER 1987

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CUMULATIVE SUPPLEMENT 11

NOVEMBER 1987

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 7th Edition (the List). The List is composed of three parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, and drug products approved by the Division of Blood and Blood Products under Section 505 of the Act.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products Approved Under Section 505 of the Act by the Division of Blood and Blood Products lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right 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 products which have had their approval 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)
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's 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. It was, therefore, placed in Category III for lack of effectiveness. A full NDA with clinical studies was submitted by Marion Laboratories, Inc., and approved by FDA, December 9, 1983. Gaviscon's activity in treating reflux acidity is made possible by the physical-chemical properties of the inactive ingredients, sodium bicarbonate and alginic acid. Therefore, all ANDAs which cite Gaviscon tablets as the listed drug must contain the inactive ingredients, sodium bicarbonate and alginic acid. A full NDA will be required to support the effectiveness of the drug product if different inactive ingredients are substituted for sodium bicarbonate or alginic acid or if different proportions of these ingredients are used.

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
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
COLMED LABORATORIES INC	PHARMACEUTICAL BASICS INC	PHARM BASICS
FORMUTEC CORP DIV COLMED LABS INC	PHARMACEUTICAL BASICS INC	PHARM BASICS

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, Tune, L., and Coyle, J.T., "Acute Extrapyramidal Side Effects: Serum Levels of Neuroleptics and Anticholinergics," Psychopharmacology, 1981;75:9-15, 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.

In Cumulative Supplement 6, of the *Approved Drug Products with Therapeutic Equivalence Evaluations*, 7th Edition, the Agency proposed to change the therapeutic equivalence code for benztropine mesylate oral tablets from BP to AA. The Agency solicited comments from interested persons to be received no later than September 30, 1987.

The proposal elicited one comment in favorable support of changing benztropine mesylate oral tablets from BP to AA.

Therefore, since there was no objection from interested parties to the proposed change, the Agency will implement its plans to designate benztropine mesylate oral tablets as AA.

Before a TE code is changed from BP to AA, applicant's with approved products are required to supplement their applications with appropriate dissolution testing.

Nortriptyline hydrochloride:

Presently, Eli Lilly and Sandoz Pharmaceuticals have received approval to market nortriptyline hydrochloride capsules, Aventyl and Pamelor, respectively. A recent article, Dubovsky, S.L., "Single Case Study: Severe Nortriptyline Intoxication due to Change from Generic to a Trade Preparation," Journal of Nervous and Mental Disease, 1987;175:115-17. indicates that it would be appropriate to change the therapeutic equivalence code for Aventyl and Pamelor from BP to BD.

The Agency will change the therapeutic equivalence code of nortriptyline hydrochloride capsules from BP to BD unless scientific data are submitted that adequately controvert the evidence presented in the cited article. The Agency is soliciting comments from interested parties who desire to submit scientific data in support of, or in disagreement with, this proposal. We request that such comments be received no later than October 30, 1987.

1.10 Revision of a Therapeutic Equivalence Evaluation

The Agency published a notice of opportunity for hearing, proposing to withdraw approval of NDAs for sterile injectable products manufactured by John D. Copanos in the Federal Register on March 10, 1987. In the Federal Register on August 6, 1987, the Agency denied a hearing and withdrew approval of these NDAs, effective September 8, 1987. The applications were withdrawn on the grounds that the methods used in, and the facilities and controls used for, the manufacture, processing and packing of the sterile injectable drugs were inadequate to assure their identity, strength, quality and purity, and were not made adequate within a reasonable time after receipt of written notice specifying the inadequacies.

Therefore, equivalence codes for those sterile injectable products manufactured by John D. Copanos are being changed from AP to BP in the August supplement and after the withdrawal of approval, the applications in the September Cumulative Supplement will be discontinued from the Prescription Drug Product List.

1.11 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 PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER[1]

CATEGORIES COUNTED	DEC 1986[2]	MAR 1987	JUN 1987	SEP 1987
DRUG PRODUCTS LISTED	8957	9183	9351	9508
SINGLE SOURCE	2103 (23.5%)	2095 (22.8%)	2089 (22.3%)	2064 (21.7%)
MULTISOURCE	6854 (76.5%)	7088 (77.2%)	7262 (77.7%)	7444 (78.3%)
THERAPEUTICALLY EQUIVALENT	5838 (65.2%)	6093 (66.4%)	6257 (67.0)	6419 (67.5%)
NOT THERAPEUTICALLY EQUIVALENT	967 (10.8%)	950 (10.3%)	946 (10.1%)	961 (10.1%)
EXCEPTIONS[3]	49 (0.5%)	45 (0.5%)	59 (0.6%)	(0.7%)
NEW MOLECULAR ENTITIES APPROVED	--	2	1	2
NUMBER OF APPLICANTS	333	334	335	341

DESCRIPTION OF ACTIVITY

	SEP 1987[1]	OCT 1987	NOV 1987
DRUG PRODUCTS ADDED:	608	63	47
NEWLY APPROVED	601	59	47
DESI EFFECTIVE	3	0	0
REMARKETED	4	4	0
DRUG PRODUCTS REMOVED:	46	0	3
PRODUCTS WITH @ SYMBOL[4]	46	0	3
RX TO OTC SWITCH	0	0	0
NET GAIN/LOSS IN DRUG PRODUCTS:	562	63	44
SINGLE SOURCE PRODUCTS APPROVED	41	8	4
MULTISOURCE PRODUCTS APPROVED	521	55	43
NEW MOLECULAR ENTITIES APPROVED:	5	1	0
AS THE ENTITY	3	0	0
AS THE SALT, ESTER OR A DERIVATIVE	2	1	0

(1) Cumulative counts are calculated from January 1, 1987 to, and including, the month indicated.
(2) Baseline figure, reflecting cumulative totals as of December 31, 1986.
(3) Amino acid-containing products of varying composition (see introduction, page I-8 of the List).
(4) Products with @ symbol include products discontinued from marketing or products which have had approval withdrawn for other than safety and effectiveness reasons.

ACETAMINOPHEN

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

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL
BANCAP
AB FOREST PHARM — 325MG;50MG — N88889 001 JAN 16, 1986

TRIAPRIN
AB DUNHALL PHARMS — 325MG;50MG¤ — N89268 001 JUL 02, 1987

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

> ADD >
> ADD >
> ADD >
> ADD >

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
BEECHAM LABS — 650MG;7.5MG¤ — N89725 001 SEP 30, 1987
AA HALSEY DRUG — 500MG;5MG¤ — N89554 001 JUN 12, 1987
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/

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
AB DANBURY PHARMA — 250MG¤ — N71893 001 NOV 25, 1987
AB — 500MG¤ — N71894 001 NOV 25, 1987

ACETYLCYSTEINE

SOLUTION; INHALATION

ACETYLCYSTEINE

AN	QUAD PHARMS	10%¤	N71740 001	
			AUG 11, 1987	
AN		20%¤	N71741 001	
			AUG 11, 1987	

ALBUTEROL SULFATE

SOLUTION; INHALATION

PROVENTIL

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

VENTOLIN

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

SYRUP; ORAL

PROVENTIL

AA	SCHERING	EQ 2MG BASE/5ML	N18062 001	
			JAN 19, 1983	

VENTOLIN

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

TABLET, CONTROLLED RELEASE; ORAL

PROVENTIL

SCHERING	EQ 4MG BASE¤	N19383 001	
		JUL 13, 1987	

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	

AMIKACIN SULFATE

INJECTABLE; INJECTION

AMIKIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

BRISTOL LABS	EQ 5MG BASE/ML¤	N50618 002		>ADD>
		NOV 30, 1987		>ADD>
	EQ 10MG BASE/ML¤	N50618 001		>ADD>
		NOV 30, 1987		>ADD>

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

AB	BIOCRAFT LABS	5MG;50MG¤	N70795 001
		APR 17, 1988 : JUL 15, 1987	

AMINO ACIDS

INJECTABLE; INJECTION

AMINOSYN 10% (PH6)

ABBOTT LABS	10%	N17673 008	
		NOV 18, 1985	

AMINOSYN 7% (PH6)

ABBOTT LABS	7%¤	N17673 006	
		NOV 18, 1985	

AMINOSYN 8.5% (PH6)

ABBOTT LABS	8.5%	N17673 007	
		NOV 18, 1985	

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	
/AB/	/INAPHARM/	/10MG/	FEB 17, 1987	
/AB/		/25MG/	/N86610/001/	
/AB/		/50MG/	/N86859/001/	
/AB/		/75MG/	/N86857/001/	
/AB/		/100MG/	/N86860/001/	
/AB/		/150MG/	/N86854/001/	
AB	LEMMON	10MG	/N86853/001/	
AB		25MG	N86610 001	
AB		50MG	N86859 001	
AB		75MG	N86857 001	
AB		100MG	N86860 001	
AB		150MG	N86854 001	
AB	MUTUAL PHARM	10MG¤	N86853 001	
AB		25MG¤	N89398 001	
AB		50MG¤	JUL 14, 1987	
AB		75MG¤	N89399 001	
AB		100MG¤	JUL 14, 1987	
AB		150MG¤	N89400 001	
			JUL 14, 1987	
			N89401 001	
			JUL 14, 1987	
			N89402 001	
			JUL 14, 1987	
			N89403 001	
			JUL 14, 1987	

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

AB	CHELSEA LABS	50MG;4MG¤	N71558 001	
>ADD> AB	CORD LABS	10MG;2MG¤	MAR 02, 1987	
>ADD>			N71062 001	
>ADD> AB		25MG;2MG¤	NOV 27, 1987	
>ADD>			N71063 001	
>ADD> AB		25MG;4MG¤	NOV 27, 1987	
>ADD>			N71064 001	
			NOV 27, 1987	

AMPHOTERICIN B

INJECTABLE; INJECTION

AMPHOTERICIN B

AP	LYPHOMED	50MG/VIAL¤	N62728 001
			APR 13, 1987

AMPHOTERICIN B

INJECTABLE; INJECTION

FUNGIZONE

AP	SQUIBB	50MG/VIAL	N60517 001

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

/AP/	/COPANGS/INC/	/EQ 125MG BASE/VIAL/	/N61936/005/
/AP/		/EQ 250MG BASE/VIAL/	/N61936/001/
/AP/		/EQ 500MG BASE/VIAL/	/N61936/002/
/AP/		/EQ 1GM BASE/VIAL/	/N61936/003/
/AP/		/EQ 2GM BASE/VIAL/	/N61936/004/
a		EQ 125MG BASE/VIAL	N61936 005
a		EQ 250MG BASE/VIAL	N61936 001
a		EQ 500MG BASE/VIAL	N61936 002
a		EQ 1GM BASE/VIAL	N61936 003
a		EQ 2GM BASE/VIAL	N61936 004
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

AB	RIKER LABS	385MG;30MG;25MG	N13416 003
			OCT 27, 1982

NORGESIC FORTE

AB	RIKER LABS	770MG;60MG;50MG	N13416 004
			OCT 27, 1982

ORPHENGESIC

AB	PAR PHARM	385MG;30MG;25MG¤	N71642 001
			JUN 23, 1987

ORPHENGESIC FORTE

AB	PAR PHARM	770MG;60MG;50MG¤	N71643 001
			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	

OINTMENT; OPHTHALMIC

	BACIGUENT			
AT	∂ UPJOHN	500 UNITS/GM¤	N60734 001	

BECLOMETHASONE DIPROPIONATE

SPRAY; INHALATION/NASAL

	BECONASE AQ			
	GLAXO	0.042MG/INH¤	N19389 001	JUL 27, 1987

BETAMETHASONE

CREAM; TOPICAL

	CELESTONE			
	∂ SCHERING	0.2%	N14762 001	

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

	BETAMETHASONE DIPROPIONATE			
AB	LEMMON	EQ 0.05% BASE¤	N71476 001	AUG 10, 1987
AB	NMC LABS	EQ 0.05% BASE¤	N70885 001	FEB 03, 1987
AB	THAMES PHARMA	EQ 0.05% BASE¤	N71143 001	JUN 17, 1987
	DIPROLENE AF			
BX	SCHERING	EQ 0.05% BASE¤	N19555 001	APR 27, 1987

LOTION; TOPICAL

	BETAMETHASONE DIPROPIONATE			
AB	LEMMON	EQ 0.05% BASE¤	N71467 001	AUG 10, 1987
AB	NMC LABS	EQ 0.05% BASE¤	N71085 001	FEB 03, 1987

OINTMENT; TOPICAL

	BETAMETHASONE DIPROPIONATE			
AB	LEMMON	EQ 0.05% BASE¤	N71477 001	AUG 10, 1987
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 /NIPPON/KAYAKU/	EQ 15 UNITS BASE/VIAL /EQ/15/UNITS/BASE/VIAL/	N50443 001 /N61843/001/	

BETAMETHASONE

CREAM; TOPICAL
CELESTONE
@ SCHERING — 0.2% — N14762 001

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
BLENOXANE
BRISTOL LABS /NIPPON/KAYAKU/ — EQ 15 UNITS BASE/VIAL /EQ/15/UNITS/BASE/VIAL/ — N50443 001 /N61847/001/

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE

AP	ASTRA PHARM PRODS	50MG/ML¤	N71151 001	AUG 10, 1987
AP		50MG/ML¤	N71152 001	AUG 10, 1987
AP		50MG/ML¤	N71153 001	AUG 10, 1987
	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

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE; INJECTION
MARCAINE HCL W/ EPINEPHRINE

AP	WINTHROP BREON	0.25%;0.0091MG/ML	N16964 004	

SENSORCAINE

AP	ASTRA PHARM PRODS	0.25%;0.0091MG/ML¤	N70966 001	OCT 13, 1987
AP		0.25%;0.0091MG/ML¤	N70967 001	OCT 13, 1987
AP		0.5%;0.0091MG/ML¤	N70968 001	OCT 13, 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
> ADD > AB	PUREPAC PHARM	200MG¤	N71696 001	NOV 09, 1987
> ADD > AB	SIDMAK LABS	200MG¤	N71479 001	JUL 24, 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

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

AP	LYPHOMED	EQ 20GM BASE/VIAL	N62688 005	AUG 03, 1987

KEFZOL

AP	LILLY	EQ 20GM BASE/VIAL¤	N61773 005	SEP 08, 1987

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION
CEFOBID IN PLASTIC CONTAINER

	ROERIG	EQ 20MG BASE/ML¤	N50613 002	JUL 31, 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

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	BARR LABS	EQ 250MG BASE¤	N62773 001 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

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

AB	MJ PHARMS	EQ 250MG BASE¤	N62791 001 JUN 11, 1987
AB		EQ 500MG BASE¤	N62791 002 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	BARR LABS	EQ 125MG BASE/5ML¤	N62778 001 AUG 06, 1987
AB		EQ 250MG BASE/5ML¤	N62777 001 AUG 06, 1987
AB	BIOCRAFT LABS	EQ 125MG BASE/5ML¤	N62703 001 FEB 13, 1987
AB		EQ 250MG BASE/5ML¤	N62703 002 FEB 13, 1987
AB	NOVOPHARM	EQ 125MG BASE/5ML¤	N62767 001 JUN 16, 1987
AB		EQ 250MG BASE/5ML¤	N62768 001 JUN 16, 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
CEPHALEXIN

AB	BARR LABS	EQ 250MG BASE¤	N62826 001 AUG 17, 1987
AB		EQ 500MG BASE¤	N62827 001 AUG 17, 1987

CEPHALEXIN

TABLET; ORAL
KEFLET
AB LILLY — EQ 250MG BASE — N50440 003 FEB 26, 1987
AB — EQ 250MG BASE — N62745 001 DEC 01, 1986
AB — EQ 500MG BASE — N50440 001
AB — EQ 500MG BASE — N62745 002 DEC 01, 1986
EQ 1GM BASE — N50440 002
/KEFLEX/ /LILLY/ /EQ 1GM BASE/ /N50440 002/

CEPHALEXIN HYDROCHLORIDE

TABLET; ORAL
KEFTAB
LILLY — EQ 250MG BASE¤ — N50614 001 OCT 29, 1987
EQ 500MG BASE¤ — N50614 002 OCT 29, 1987

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
CEPHALOTHIN SODIUM
AP LYPHOMED — EQ 1GM BASE/VIAL¤ — N62666 002 JUN 10, 1987
AP — EQ 2GM BASE/VIAL¤ — N62666 001 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

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION
CEPHAPIRIN SODIUM
AP ELKINS SINN — EQ 500MG BASE/VIAL¤ — N62720 001 JUL 02, 1987
AP — EQ 1GM BASE/VIAL¤ — N62720 002 JUL 02, 1987
AP — EQ 2GM BASE/VIAL¤ — N62720 003 JUL 02, 1987
AP — EQ 20GM BASE/VIAL¤ — N62720 004 JUL 02, 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

POWDER FOR RECONSTITUTION; ORAL
CEPHRADINE
AB BIOCRAFT LABS — 125MG/5ML¤ — N62693 001 JAN 09, 1987
AB — 250MG/5ML¤ — N62693 002 JAN 09, 1987

CHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
ALDOCLOR-150
> ADD > AB MS&D — 150MG;250MG — N16016 001
ALDOCLOR-250
> ADD > AB MS&D — 250MG;250MG — N16016 002
> ADD >
METHYLDOPA AND CHLOROTHIAZIDE
> ADD > AB PAR PHARM — 150MG;250MG¤ — N70783 001 NOV 06, 1987
> ADD >
> ADD > AB — 250MG;250MG¤ — N70654 001 NOV 06, 1987
> ADD >

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION
CHLOR-TRIMETON
AP ∂ SCHERING — 100MG/ML — N08794 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, CONTROLLED RELEASE; ORAL
CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL
BC CHELSEA LABS — 12MG;75MG¤ — N88681 001 SEP 29, 1987

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

AB	LEDERLE LABS	100MG*	N89561 001 SEP 04, 1987
AB		250MG*	N89562 001 SEP 04, 1987

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

AB	COLMED LABS	25MG*	N89051 001 JUN 01, 1987
AB		50MG*	N89052 001 JUN 01, 1987
AB	VITARINE	50MG	N87118 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

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

AA	AMIDE PHARM	250MG*	N88928 001 MAY 08, 1987
	PARAFON FORTE DSC MCNEIL PHARM	500MG*	N11529 002 JUN 15, 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

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL
CIPRO
MILES PHARM

EQ 250MG BASE*	N19537 002 OCT 22, 1987
EQ 500MG BASE*	N19537 003 OCT 22, 1987
EQ 750MG BASE*	N19537 004 OCT 22, 1987

CLAVULANATE POTASSIUM; TICARCILLIN DISODIUM

INJECTABLE; INJECTION
TIMENTIN
BEECHAM LABS

EQ 1GM ACID/VIAL; EQ 30GM BASE/VIAL*	N50590 003 AUG 18, 1987

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
CLEOCIN T
UPJOHN

EQ 1% BASE*	N50615 001 JAN 07, 1987

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLEOCIN PHOSPHATE

AP	UPJOHN	EQ 150MG BASE/ML¤	N62803 001	OCT 16, 1987
AP	UPJOHN MFG	EQ 150MG BASE/ML¤	N61839 001	

CLINDAMYCIN PHOSPHATE

AP	ABBOTT LABS	EQ 150MG BASE/ML¤	N62800 001	JUL 24, 1987
AP		EQ 150MG BASE/ML¤	N62801 001	JUL 24, 1987
AP	ELKINS SINN	EQ 150MG BASE/ML¤	N62806 001	OCT 15, 1987

CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

AB	CHELSEA LABS	500MG¤	N71603 001	SEP 18, 1987

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

AB	BARR LABS	0.1MG¤	N70925 001	SEP 04, 1987
AB		0.2MG¤	N70924 001	SEP 04, 1987
AB		0.3MG¤	N70923 001	SEP 04, 1987
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
AB	MYLAN PHARMS	0.1MG¤	N70315 001	JUN 09, 1987
AB		0.2MG¤	N70316 001	JUN 09, 1987
AB		0.3MG¤	N70317 001	JUN 09, 1987

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

AB	ABLE LABS	3.75MG¤	N71777 001	JUL 14, 1987
AB		7.5MG¤	N71778 001	JUL 14, 1987
AB		15MG¤	N71779 001	JUL 14, 1987
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
AB	MYLAN PHARMS	3.75MG¤	N71509 001	OCT 19, 1987
AB		7.5MG¤	N71510 001	OCT 19, 1987
AB		15MG¤	N71511 001	OCT 19, 1987

TRANXENE

ə	ABBOTT LABS	3.75MG	N17105 001
ə		7.5MG	N17105 002
ə		15MG	N17105 003

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

AB	ABLE LABS	3.75MG¤	N71780 001	JUN 26, 1987
AB		7.5MG¤	N71781 001	JUN 26, 1987
AB		15MG¤	N71782 001	JUN 26, 1987
AB	AM THERPTCS	3.75MG¤	N71747 001	JUN 23, 1987 : JUN 09, 1987
AB		7.5MG¤	N71748 001	JUN 23, 1987 : JUN 09, 1987
AB		15MG¤	N71749 001	JUN 23, 1987 : JUN 09, 1987
AB	MYLAN PHARMS	3.75MG¤	N71856 001	JUL 17, 1987
AB		7.5MG¤	N71857 001	JUL 17, 1987
AB		15MG¤	N71858 001	JUL 17, 1987

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

	CLORAZEPATE DIPOTASSIUM			
AB	QUANTUM PHARMCS	3.75MG¤	N71730 001	OCT 26, 1987
AB		7.5MG¤	N71731 001	OCT 26, 1987
AB		15MG¤	N71702 001	OCT 26, 1987
	TRANXENE			
AB	ABBOTT LABS	3.75MG	N17105 006	
AB		7.5MG	N17105 007	
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

	DESIPRAMINE HCL			
AB	PHARM BASICS	25MG¤	N71864 001	SEP 09, 1987
AB		50MG¤	N71865 001	SEP 09, 1987
AB		75MG¤	N71866 001	SEP 09, 1987
AB		100MG¤	N71867 001	SEP 09, 1987
AB	VITARINE	25MG¤	N71601 001	JUN 05, 1987
AB		50MG¤	N71588 001	JUN 05, 1987
AB		75MG¤	N71602 001	OCT 05, 1987
AB		100MG¤	N71766 001	OCT 05, 1987
	NORPRAMIN			
AB	MERRELL DOW	25MG	N14399 001	
AB		50MG	N14399 003	
AB		75MG	N14399 004	
AB		100MG	N14399 005	

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

DEXCHLORPHENIRAMINE MALEATE

TABLET; ORAL

	DEXCHLORPHENIRAMINE MALEATE			
AA	SIDMAK LABS	2MG	N88682 001	JAN 17, 1986
/~~AB~~/		/~~2MG~~/	/~~N88682~~/001/	/JAN/17/1986/
	POLARAMINE			
AA	SCHERING	2MG	N86835 001	
/~~AB~~/		/~~2MG~~/	/~~N86835~~/001/	

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

INJECTABLE; INJECTION

	DIAZEPAM			
AP	ABBOTT LABS	5MG/ML¤	N71583 001	OCT 13, 1987
AP		5MG/ML¤	N71584 001	OCT 13, 1987
AP	LEDERLE LABS	5MG/ML¤	N71308 001	JUL 17, 1987
AP		5MG/ML¤	N71309 001	JUL 17, 1987
AP		5MG/ML¤	N71310 001	JUL 17, 1987
AB	PARKE DAVIS	5MG/ML¤	N71614 001	OCT 22, 1987
AP		5MG/ML¤	N71613 001	OCT 22, 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

DIAZOXIDE

INJECTABLE; INJECTION

	DIAZOXIDE			
AP	LYPHOMED	15MG/ML¤	N71519 001	AUG 26, 1987
	HYPERSTAT			
AP	SCHERING	15MG/ML	N16996 001	

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

	DICYCLOMINE HCL			
AB	BARR LABS	10MG	N84505 001	OCT 21, 1986

DIFLORASONE DIACETATE

CREAM; TOPICAL

	DIFLORASONE DIACETATE			
	/S/UPJOHN/	/0.05%/	/N19259/001/	/AUG/28,/1985/
	UPJOHN	0.05%	N19259 001	AUG 28, 1985
	FLORONE			
	UPJOHN	0.05%	N17741 001	

OINTMENT; TOPICAL

	DIFLORASONE DIACETATE			
	/S/UPJOHN/	/0.05%/	/N19260/001/	/AUG/28,/1985/
	UPJOHN	0.05%	N19260 001	AUG 28, 1985
	FLORONE			
	UPJOHN	0.05%	N17994 001	

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

	DIPHENHYDRAMINE HCL			
AA	MUTUAL PHARM	25MG¤	N89488 001	JAN 02, 1987
AA		50MG¤	N89489 001	JAN 02, 1987
	/S/WEST-WARD/	/50MG/	/N83567/001/	
AA	WEST WARD	50MG	N83567 001	

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
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
>ADD> AB	PAR PHARM	EQ 10MG BASE¤	N71697 001	NOV 09, 1987
>ADD> AB		EQ 25MG BASE¤	N71437 001	NOV 09, 1987
>ADD> AB		EQ 50MG BASE¤	N71595 001	NOV 09, 1987
>ADD> AB		EQ 75MG BASE¤	N71608 001	NOV 09, 1987
>ADD> AB		EQ 100MG BASE¤	N71422 001	NOV 09, 1987
>ADD> AB		EQ 150MG BASE¤	N71669 001	NOV 09, 1987
AB	QUANTUM PHARMCS	EQ 10MG BASE¤	N70972 001	SEP 29, 1987
AB		EQ 25MG BASE¤	N70973 001	SEP 29, 1987
AB		EQ 50MG BASE¤	N70931 001	SEP 29, 1987
AB		EQ 75MG BASE¤	N70932 001	SEP 29, 1987

SINEQUAN

>ADD> AB	PFIZER LABS	EQ 150MG BASE	N16798 007	

CONCENTRATE; ORAL
DOXEPIN HCL

>ADD> AA	COPLEY PHARM	EQ 10MG BASE/ML¤	N71609 001	NOV 09, 1987

SINEQUAN

>ADD> AA	PFIZER LABS	EQ 10MG BASE/ML	N17516 001	

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

/ADRIAMYCIN/			
/FARMITALIA/	/10MG/VIAL/		/N50467/001/
	/20MG/VIAL/		/N50467/003/
			/MAY/20,/1985/
	/50MG/VIAL/		/N50467/002/
ADRIAMYCIN RDF			
FARMITALIA	10MG/VIAL		N50467 001
	20MG/VIAL		N50467 003
			MAY 20, 1985
	50MG/VIAL		N50467 002
	150MG/VIAL*		N50467 004
			JUL 22, 1987

ENFLURANE

LIQUID; INHALATION

	ENFLURANE		
AN	ABBOTT LABS	99.9%*	N70803 001
			SEP 08, 1987 : JUL 27, 1987
	ETHRANE		
AN	ANAQUEST	99.9%	N17087 001

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

GEL; TOPICAL

	ERYGEL		
	HERBERT LABS	2%*	N50617 001
			OCT 21, 1987

SOLUTION; TOPICAL

	MYTHROMYCIN		
AT	MY K LABS	2%*	N62825 001
			OCT 23, 1987

SWAB; TOPICAL

	ERYCETTE		
AT	ORTHO PHARM	2%	N50594 001
			FEB 15, 1985

ERYTHROMYCIN

SWAB; TOPICAL

	T-STAT		
AT	WESTWOOD PHARMS	2%*	N62748 001
			JUL 23, 1987

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

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

ESTRADIOL CYPIONATE

INJECTABLE; INJECTION

	ESTRADIOL CYPIONATE		
AQ	QUAD PHARMS	5MG/ML*	N89310 001
			FEB 09, 1987

ESTROGENS, CONJUGATED

TABLET; ORAL

	CONJUGATED ESTROGENS		
/BS//@/CHELSEA/LABS/		/0.625MG/	/N85800/001/
BS	CHELSEA LABS	0.625MG	N85800 001
/BS//@/		/1.25MG/	/N85801/001/
BS		1.25MG	N85801 001
/BS//@/		/2.5MG/	/N85826/001/
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/

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHINDRONE AND ETHINYL ESTRADIOL

AB	WATSON LABS	0.035MG;1MG¤	N70685 001 JAN 29, 1987
AB		0.035MG;0.5MG¤	N70684 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/

NORETHINDRONE AND ETHINYL ESTRADIOL

AB	WATSON LABS	0.035MG;1MG¤	N70687 001 JAN 29, 1987
AB		0.035MG;0.5MG¤	N70686 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

FLOXURIDINE

INJECTABLE; INJECTION
FLOXURIDINE

AP	QUAD PHARMS	500MG/VIAL¤	N71055 001 AUG 24, 1987

FLOXURIDINE

INJECTABLE; INJECTION
FUDR

AP	ROCHE	500MG/VIAL	N16929 001

FLUNISOLIDE

AEROSOL, METERED; INHALATION
AEROBID

	/KEY PHARMS/	/0.025MG/INH/	/N18340 001/ /AUG 17, 1984/
	KEY PHARMS	0.25MG/INH	N18340 001 AUG 17, 1984

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

AB	THAMES PHARMA	0.05%¤	N71500 001 JUN 10, 1987

FLUOROMETHOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC
FLAREX

	ALCON LABS	0.1%	N19079 001 FEB 11, 1986

/OMNITROL/

	/ALCON LABS/	/0.1%/	/N19619 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
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 DECANOATE

INJECTABLE; INJECTION

	FLUPHENAZINE DECANOATE			
AO	LYPHOMED	25MG/ML¤	N71413 001	JUL 14, 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	

TABLET; ORAL

	FLUPHENAZINE HCL			
AB	CORD LABS	1MG¤	N89583 001	OCT 16, 1987
AB		2.5MG¤	N89584 001	OCT 16, 1987
AB		5MG¤	N89585 001	OCT 16, 1987
AB		10MG¤	N89586 001	OCT 16, 1987
	PROLIXIN			
AB	SQUIBB	1MG	N11751 004	
AB		2.5MG	N11751 001	
AB		5MG	N11751 003	
AB		10MG	N11751 002	
/BP/		/1MG/	/N11751/004/	
/BP/		/2.5MG/	/N11751/001/	
/BP/		/5MG/	/N11751/003/	
/BP/		/10MG/	/N11751/002/	

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

	FLURAZEPAM HCL			
AB	COLMED LABS	15MG¤	N70562 001	JUL 09, 1987
AB		30MG¤	N70563 001	JUL 09, 1987
AB	PUREPAC PHARM	15MG¤	N71927 001	SEP 09, 1987
AB		30MG¤	N71551 001	SEP 09, 1987

FUROSEMIDE

INJECTABLE; INJECTION

	FUROSEMIDE			
AP	CARTER GLOGAU	10MG/ML¤	N70604 001	JAN 02, 1987
AP	WINTHROP BREON	10MG/ML¤	N70578 001	JUL 08, 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	
	MYROSEMIDE			
AA	MY K LABS	10MG/ML¤	N70655 001	OCT 02, 1987

TABLET; ORAL

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

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GENTAMICIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	EQ 40MG BASE/100ML¤	N62814 008 AUG 28, 1987
AP		EQ 60MG BASE/100ML¤	N62814 009 AUG 28, 1987
AP		EQ 70MG BASE/100ML¤	N62814 010 AUG 28, 1987
AP		EQ 0.8MG BASE/ML¤	N62814 001 AUG 28, 1987
AP		EQ 80MG BASE/100ML¤	N62814 011 AUG 28, 1987
AP		EQ 90MG BASE/100ML¤	N62814 012 AUG 28, 1987
AP		EQ 100MG BASE/100ML¤	N62814 013 AUG 28, 1987
AP		EQ 1.2MG BASE/ML¤	N62814 002 AUG 28, 1987
AP		EQ 120MG BASE/100ML¤	N62814 014 AUG 28, 1987
AP		EQ 1.4MG BASE/ML¤	N62814 003 AUG 28, 1987
AP		EQ 1.6MG BASE/ML¤	N62814 004 AUG 28, 1987
AP		EQ 1.8MG BASE/ML¤	N62814 005 AUG 28, 1987
AP		EQ 2MG BASE/ML¤	N62814 006 AUG 28, 1987
AP		EQ 2.4MG BASE/ML¤	N62814 007 AUG 28, 1987

ISOTONIC GENTAMICIN SULFATE IN PLASTIC CONTAINER

AP	TRAVENOL LABS	EQ 40MG BASE/100ML	N62373 003 SEP 07, 1982
AP		EQ 2.4MG BASE/ML	N62373 010 SEP 07, 1982

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

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION
GLUCAGON

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

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	DURAMED PHARMS	10MG¤	N71220 001 JUL 07, 1987
AB		20MG¤	N71221 001 JUL 07, 1987
AB	PAR PHARM	10MG¤	N71237 001 JUL 20, 1987
AB		20MG¤	N71328 001 JUL 20, 1987
AB	PUREPAC PHARM	10MG¤	N71075 001 AUG 04, 1987
AB		20MG¤	N71076 001 AUG 04, 1987

HALOPERIDOL

TABLET; ORAL

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

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

	HALOPERIDOL			
AA	LEMMON	EQ 2MG BASE/ML¤	N71015 001	AUG 25, 1987

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 LOCK FLUSH PRESERVATIVE FREE			
AP	LYPHOMED	10 UNITS/ML¤	N17029 011	SEP 22, 1987
AP		100 UNITS/ML¤	N17029 012	SEP 22, 1987

HEPARIN SODIUM

INJECTABLE; INJECTION

	HEPARIN LOCK FLUSH PRESERVATIVE FREE IN PLASTIC CONTAINER			
AP	LYPHOMED	10 UNITS/ML¤	N17029 008	SEP 22, 1987
AP		100 UNITS/ML¤	N17029 009	SEP 22, 1987
	HEPARIN SODIUM PRESERVATIVE FREE			
AP	WINTHROP BREON	10,000 UNITS/ML¤	N89522 001	MAY 04, 1987
	HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER			
	TRAVENOL LABS	2,000 UNITS/100ML	N18814 002	JUL 09, 1985
	HEPARIN SODIUM 25,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER			
AP	TRAVENOL LABS	5,000 UNITS/100ML	N18814 003	JUL 09, 1985
AP		10,000 UNITS/100ML¤	N18814 004	JUL 02, 1987

HEXACHLOROPHENE

EMULSION; TOPICAL

	SOY-DOME			
AT	∂ MILES PHARM	3%	N17405 001	

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

	HYDRALAZINE HCL			
AP	LYPHOMED	20MG/ML¤	N89532 001	AUG 11, 1987

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

HORMOZIDE

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	
> ADD > AB	PARKE DAVIS	15MG;250MG¤	N71897 001	NOV 23, 1987	
> ADD > AB		25MG;250MG¤	N71898 001	NOV 23, 1987	
> ADD > AB		30MG;500MG¤	N71899 001	NOV 23, 1987	
> ADD > AB		50MG;500MG¤	N71900 001	NOV 23, 1987	

HYDROCHLOROTHIAZIDE; PINDOLOL

TABLET; ORAL

VISKAZIDE

	SANDOZ PHARMS	25MG;5MG¤	N18872 001	JUL 22, 1987
		25MG;10MG¤	N18872 002	JUL 22, 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

PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

AB	CORD LABS	25MG;40MG¤	N71060 001	AUG 26, 1987
AB		25MG;80MG¤	N71061 001	AUG 26, 1987
AB	MYLAN PHARMS	25MG;40MG¤	N70946 001	MAR 04, 1987
AB		25MG;80MG¤	N70947 001	APR 01, 1987

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

AB	MUTUAL PHARM	25MG;25MG¤	N89534 001	JUL 02, 1987

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

DYAZIDE

AB	SK&F LABS	25MG;50MG	N16042 002	

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	BOLAR PHARM	25MG;50MG¤	N71845 001	AUG 21, 1987

TABLET; ORAL

MAXZIDE

> ADD > AB	MYLAN PHARMS	50MG;75MG	N19129 001	OCT 22, 1984

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

> ADD > AB	AM THERPTCS	50MG;75MG¤	*N72022 001*	*APR 17, 1988 : NOV 03, 1987*

HYDROCORTISONE

OINTMENT; TOPICAL

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

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OTIC

	PEDIOTIC CORTISPORIN			
AT	BURROUGHS WELLC	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML¤	N62822 001	SEP 29, 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	CHELSEA LABS	800MG¤	N71911 001	OCT 13, 1987
AB	DANBURY PHARMA	800MG¤	N71547 001	JUL 02, 1987
AB	HALSEY DRUG	300MG¤	N71028 001	MAR 23, 1987
AB		400MG¤	N71029 001	MAR 23, 1987
AB		600MG¤	N71030 001	MAR 23, 1987
AB	INTERPHARM	800MG¤	N71935 001	OCT 13, 1987
>ADD> AB	MUTUAL PHARM	800MG¤	N72004 001	NOV 18, 1987
>ADD> AB	SIDMAK LABS	400MG¤	N71666 001	JUN 18, 1987
AB		600MG¤	N71667 001	JUN 18, 1987
AB		800MG¤	N71668 001	JUN 18, 1987
	IFEN			
AB	LUCHEM PHARMS	800MG¤	N71769 001	MAY 08, 1987

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

	IMIPRAMINE HCL			
AB	PAR PHARM	10MG¤	N89422 001	JUL 14, 1987
AB		25MG¤	N89497 001	JUL 14, 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
AB	HALSEY DRUG	25MG¤	N70782 001	JUN 03, 1987
AB		50MG¤	N70635 001	JUN 03, 1987
AB	MUTUAL PHARM	25MG¤	N70899 001	FEB 09, 1987
AB		50MG¤	N70900 001	FEB 09, 1987
AB	SIDMAK LABS	25MG¤	N71148 001	MAR 18, 1987
AB		50MG¤	N71149 001	MAR 18, 1987

CAPSULE, CONTROLLED RELEASE; ORAL

INDOCIN SR

AB	MS&D RES LABS	75MG	N18185 001	FEB 23, 1982

INDOMETHACIN

AB	VITARINE	75MG¤	N71531 001	JUL 21, 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

INULIN

INJECTABLE; INJECTION

INULIN AND SODIUM CHLORIDE

	ISO TEX DIAGS	100MG/ML	N02282 001	
	/PURIFIED INULIN/ DUPONT/CRI/CARE/	/100MG/ML/	/N02282/001/	

IOPAMIDOL

INJECTABLE; INJECTION

ISOVUE-200

SQUIBB DIAGS	41%	N18735 001	DEC 31, 1985
/ISOVUE-M/200/ /SQUIBB/	/41%/	/N18735/001/	/DEC 31, 1985/

ISOVUE-128

SQUIBB DIAGS	26%¤	N18735 005	OCT 21, 1986

IRON DEXTRAN

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	PAR PHARM	5MG¤	N86923 001	MAR 12, 1987
AB		10MG¤	N86925 001	MAR 12, 1987
AB		20MG¤	N87537 001	OCT 02, 1987
AB	SUPERPHARM	5MG¤	N89190 001	FEB 17, 1987
AB		10MG¤	N89191 001	FEB 17, 1987
AB		20MG¤	N89192 001	FEB 17, 1987
AB	WEST WARD	5MG¤	N86067 001	OCT 29, 1987
AB		10MG¤	N86066 001	OCT 29, 1987
> ADD > AB		20MG¤	N88088 001	NOV 02, 1987
> ADD >				

ISOSORBIDE DINITRATE

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE

AB	BARR LABS	2.5MG	N84204 001	SEP 18, 1986
>ADD > AB		5MG	N86168 001	SEP 18, 1986
>ADD > AB	WEST WARD	2.5MG¤	N86054 001	OCT 29, 1987
>ADD > AB		5MG¤	N86055 001	NOV 02, 1987

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX

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

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

KETOCONAZOLE

CREAM; TOPICAL
NIZORAL

	JANSSEN PHARMA	2%¤	N19084 001	DEC 31, 1985
		2%¤	N19576 001	OCT 22, 1987
		2%¤	N19648 001	SEP 25, 1987

KETOPROFEN

CAPSULE; ORAL
ORUDIS

AB	WYETH	25MG¤	N18754 001	JUL 31, 1987

LABETALOL HYDROCHLORIDE

TABLET; ORAL
NORMODYNE

AB	SCHERING	100MG¤	N18687 001	AUG 31, 1987

TRANDATE

AB	GLAXO	100MG	N18716 001	MAY 24, 1985

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

AP	BEN VENUE LABS	EQ 50MG BASE/VIAL¤	N89384 001	SEP 14, 1987
AP	ELKINS SINN	EQ 50MG BASE/VIAL¤	N70480 001	JAN 02, 1987
AP	QUAD PHARMS	EQ 5MG BASE/ML¤	N89503 001	OCT 05, 1987
AP		EQ 50MG BASE/VIAL¤	N89496 001	MAR 05, 1987

WELLCOVORIN

AP	BURROUGHS WELLC	EQ 5MG BASE/ML	N87439 001	OCT 19, 1982

POWDER FOR RECONSTITUTION; ORAL
LEUCOVORIN CALCIUM

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

TABLET; ORAL
LEUCOVORIN CALCIUM

AB	BARR LABS	EQ 5MG BASE¤	N71198 001	SEP 24, 1987
AB		EQ 25MG BASE¤	N71199 001	SEP 24, 1987
>ADD >	LEDERLE LABS	EQ 10MG BASE¤	N71962 001	NOV 19, 1987
>ADD >		EQ 15MG BASE¤	N71104 001	MAR 04, 1987
AB	PAR PHARM	EQ 5MG BASE¤	N71600 001	OCT 14, 1987
AB		EQ 25MG BASE¤	N71598 001	OCT 14, 1987

WELLCOVORIN

AB	BURROUGHS WELLC	EQ 5MG BASE	N18342 001	JUL 08, 1983
AB		EQ 25MG BASE	N18342 002	JUL 08, 1983

/BX/ /EQ/5MG/BASE/ /N18342/001/ /JUL/08/1983/

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

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

LORAZEPAM

TABLET; ORAL
LORAZEPAM

AB	HALSEY DRUG	0.5MG¤	N71434 001	SEP 01, 1987
AB		1MG¤	N71435 001	SEP 01, 1987
AB		2MG¤	N71436 001	SEP 01, 1987
AB	MYLAN PHARMS	0.5MG¤	N71589 001	OCT 13, 1987
AB		1MG¤	N71590 001	OCT 13, 1987
AB		2MG¤	N71591 001	OCT 13, 1987
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	MATSON LABS	0.5MG¤	N71086 001	MAR 23, 1987
AB		1MG¤	N71087 001	MAR 23, 1987
AB		2MG¤	N71088 001	MAR 23, 1987

LOVASTATIN

TABLET; ORAL
MEVACOR

	MS&D RES LABS	20MG¤	N19643 003	AUG 31, 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
MECLODIUM

AB	QUANTUM PHARMCS	EQ 50MG BASE¤	N71380 001	JUL 14, 1987
AB		EQ 100MG BASE¤	N71381 001	JUL 14, 1987

MECLOFENAMATE SODIUM

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

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM

AB	CHELSEA LABS	EQ 50MG BASE¤	N71640 001	AUG 11, 1987
AB		EQ 100MG BASE¤	N71641 001	AUG 11, 1987
AB	DANBURY PHARMA	EQ 50MG BASE¤	N71468 001	APR 15, 1987
AB		EQ 100MG BASE¤	N71469 001	APR 15, 1987

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL
CYCRIN

AB	AYERST LABS	10MG¤	N89386 001	SEP 09, 1987

PROVERA

AB /BP/	UPJOHN	10MG /10MG/	N11839 004 /N11839/004/	

MEGESTROL ACETATE

TABLET; ORAL
MEGACE

AB	MEAD JOHNSON	20MG	N16979 001	
AB		40MG	N16979 002	

MEGESTROL ACETATE

AB	COLMED LABS	20MG¤	N70646 001	OCT 02, 1987
AB		40MG¤	N70647 001	OCT 02, 1987

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE

>ADD> AA >ADD>	KM LABS	400MG¤	N89538 001	NOV 25, 1987

METAPROTERENOL SULFATE

SOLUTION; INHALATION
ALUPENT

AN	BOEHR INGEL	0.6%	N18761 001	JUN 30, 1983
AN		5%	N17659 001	

METAPROTERENOL SULFATE

SOLUTION; INHALATION
METAPROTERENOL SULFATE

AN	DEY LABS	0.6%¤	N70804 001	AUG 17, 1987
AN		5%¤	N70805 001	AUG 17, 1987

SYRUP; ORAL
ALUPENT

AA	BOEHR INGEL	10MG/5ML	N17571 001	

METAPROTERENOL SULFATE

AA	MY K LABS	10MG/5ML¤	N71656 001	OCT 13, 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
ABITREXATE

AP	INTL PHARM	EQ 25MG BASE/ML¤	N89161 001	MAR 10, 1987
AP		EQ 50MG BASE/VIAL¤	N89354 001	JUL 17, 1987
AP		EQ 100MG BASE/VIAL¤	N89355 001	JUL 17, 1987
AP		EQ 250MG BASE/VIAL¤	N89356 001	JUL 17, 1987

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
AP		50MG/ML¤	N70699 001 JUN 15, 1987
AP	DUPONT CRI CARE	50MG/ML¤	N70691 001 JUN 19, 1987
AP		50MG/ML¤	N70849 001 JUN 19, 1987
AP	LUITPOLD PHARMS	50MG/ML¤	N71279 001 OCT 02, 1987
AP	SOLOPAK LABS	50MG/ML¤	N70841 001 JAN 02, 1987

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE ACETATE

>DLT>	/BP/	/LEMMON/	/20MG/ML/	/N87248/001/
>DLT>	/BP/		/40MG/ML/	/N85374/001/
>DLT>	/BP/		/80MG/ML/	/N86507/001/
>ADD>		ə	20MG/ML	N87248 001
>ADD>		ə	40MG/ML	N85374 001
>ADD>		ə	80MG/ML	N86507 001

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-METHAPRED

AP	ABBOTT LABS	EQ 500MG BASE/VIAL¤	N89173 001 AUG 18, 1987
AP		EQ 1GM BASE/VIAL¤	N89174 001 AUG 18, 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

SYRUP; ORAL
METOCLOPRAMIDE HCL

AA	BIOCRAFT LABS	EQ 5MG BASE/5ML¤	N70819 001 JUL 10, 1987
AA	MY K LABS	EQ 5MG BASE/5ML¤	N70949 001 MAR 06, 1987
AA	REGLAN 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
AB	MARTEC PHARMS	EQ 10MG BASE¤	N70598 001 FEB 02, 1987
AB	SUPERPHARM	EQ 10MG BASE¤	N70926 001 JUN 26, 1987
AB	WATSON LABS	EQ 10MG BASE¤	N70645 001 MAY 11, 1987
	REGLAN ROBINS	EQ 5MG BASE¤	N17854 002 MAY 05, 1987

METOLAZONE

TABLET; ORAL
MICROX
PENNWALT 0.5MG¤ N19532 001 OCT 30, 1987

METRIZAMIDE

INJECTABLE; INJECTION
AMIPAQUE
WINTHROP BREON
2.5GM/VIAL N17982 003 > ADD > AB
SEP 12, 1983
13.5GM/VIAL N17982 004 > ADD > AB
SEP 12, 1983

METRONIDAZOLE

TABLET; ORAL
SATRIC
AB SAVAGE LABS 500MG℞ N70731 001
JUN 08, 1987

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION
MEZLIN
MILES PHARM
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
AB 10MG℞ MAR 03, 1987
N71345 001
MAR 03, 1987

MINOXIDIL

TABLET; ORAL
MINOXIDIL
ROYCE LABS 2.5MG℞ N71799 001
NOV 10, 1987
10MG℞ N71796 001
NOV 10, 1987

MOLINDONE HYDROCHLORIDE

TABLET; ORAL
MOBAN
~~/3/DUPONT/PHARMS/~~ ~~/100MG/~~ ~~/N17111/008/~~
DUPONT PHARMS 100MG N17111 008

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
>ADD> AP	SOLOPAK LABS	0.02MG/ML¤	N71671 001	NOV 17, 1987
>ADD> AP		0.02MG/ML¤	N71672 001	NOV 17, 1987
>ADD> AP		0.4MG/ML¤	N71681 001	NOV 17, 1987
>ADD> AP		0.4MG/ML¤	N71682 001	NOV 17, 1987
>ADD> AP		0.4MG/ML¤	N71683 001	NOV 17, 1987
>ADD> AP	STERIS LABS	0.4MG/ML¤	N71339 001	NOV 18, 1987

NAPROXEN

SUSPENSION; ORAL
NAPROSYN

	SYNTEX LABS	25MG/ML¤	N18965 001	MAR 23, 1987

NAPROXEN SODIUM

TABLET; ORAL
ANAPROX

	SYNTEX PR	550MG¤	N18164 003	SEP 30, 1987

NITROGLYCERIN

INJECTABLE; INJECTION
NITROGLYCERIN

AP	LYPHOMED	5MG/ML¤	N71203 001	MAY 08, 1987

NITROGLYCERIN

INJECTABLE; INJECTION
NITROGLYCERIN

AP	QUAD PHARMS	5MG/ML¤	N71094 001	JUL 31, 1987
AP		10MG/ML¤	N71095 001	JUL 31, 1987

NITROSTAT

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

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
PAMELOR

	SANDOZ PHARMS	EQ 50MG BASE	N18013 004	

NYSTATIN

OINTMENT; TOPICAL
NYSTATIN

>ADD> AT	NASKA PHARMA	100,000 UNITS/GM¤	N62840 001	NOV 13, 1987

PASTILLE; ORAL
MYCOSTATIN

	SQUIBB	200,000 UNITS¤	N50619 001	APR 09, 1987

SUSPENSION; ORAL
NYSTATIN

AA	BIOCRAFT LABS	100,000 UNITS/ML¤	N62670 001	JUN 18, 1987
>ADD> AA	MY K LABS	100,000 UNITS/ML¤	N62835 001	NOV 19, 1987

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN-TRIAMCINOLONE ACETONIDE

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

NYSTATIN; TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

MYKACET

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

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

BP	BARR LABS	10MG	N70957 001 AUG 10, 1987
BP		15MG	N71025 001 AUG 10, 1987
BP		30MG	N71026 001 AUG 10, 1987
BP	ZENITH LABS	10MG	N70943 001 AUG 03, 1987
BP		15MG	N70944 001 AUG 03, 1987
BP		30MG	N70945 001 AUG 03, 1987

SERAX

BP	WYETH	10MG	N15539 002
BP		15MG	N15539 004
BP		30MG	N15539 006

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

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

AP	COPANOS INC	500,000 UNITS/VIAL	N60806 001
AP		1,000,000 UNITS/VIAL	N60806 002
AP		5,000,000 UNITS/VIAL	N60806 003
AP		10,000,000 UNITS/VIAL	N60806 004

a 500,000 UNITS/VIAL N60806 001
a 1,000,000 UNITS/VIAL N60806 002
a 5,000,000 UNITS/VIAL N60806 003
a 10,000,000 UNITS/VIAL N60806 004

PENICILLIN G PROCAINE

INJECTABLE; INJECTION

PENICILLIN G PROCAINE

AP	COPANOS INC	300,000 UNITS/ML	N60800 001
AP		600,000 UNITS/1.2ML	N60800 002

a 300,000 UNITS/ML N60800 001
a 600,000 UNITS/1.2ML N60800 002

PENICILLIN G SODIUM

INJECTABLE; INJECTION

PENICILLIN G SODIUM

AP	COPANOS INC	5,000,000 UNITS/VIAL	N61051 001

a COPANOS INC 5,000,000 UNITS/VIAL N61051 001

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

AB	ZENITH LABS	2MG	N89707 001 SEP 10, 1987
AB		4MG	N89708 001 SEP 10, 1987
AB		8MG	N89456 001 SEP 10, 1987
AB		16MG	N89457 001 SEP 10, 1987

TRILAFON

AB	SCHERING	2MG	N10775 001
AB		4MG	N10775 002
AB		8MG	N10775 003
AB		16MG	N10775 004

PHENAZOPYRIDINE HYDROCHLORIDE; SULFAMETHOXAZOLE

TABLET; ORAL

AZO GANTANOL

	ROCHE	100MG;500MG	N13294 001 SEP 10, 1987

PHENTERMINE HYDROCHLORIDE

TABLET; ORAL

UMI-PEX 30

	FERNDALE LABS	30MG	N88605 001 SEP 28, 1987

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
AP MARSAM PHARMS 50MG/ML¤ N89501 001 OCT 13, 1987

PIPERACILLIN SODIUM

INJECTABLE; INJECTION
PIPRACIL
LEDERLE LABS EQ 2GM BASE/VIAL¤ N62750 001 OCT 13, 1987
EQ 3GM BASE/VIAL¤ N62750 002 OCT 13, 1987
EQ 4GM BASE/VIAL¤ N62750 003 OCT 13, 1987
LEDERLE PIPRCLN EQ 2GM BASE/VIAL¤ N50545 002
EQ 3GM BASE/VIAL¤ N50545 003
EQ 4GM BASE/VIAL¤ N50545 004

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

POWDER FOR RECONSTITUTION; ORAL
COLYTE
REED & CARNRICK 240GM/BOT;2.98GM/BOT;6.72GM/BOT; 5.84GM/BOT;22.72GM/BOT¤ N18983 007 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

TABLET, CONTROLLED RELEASE; ORAL
K+10
BC ALRA LABS 10MEQ¤ N70999 001 OCT 22, 1987

POTASSIUM CHLORIDE
AB COPLEY PHARM 8MEQ¤ N70618 001 SEP 09, 1987

SLOW-K
AB CIBA PHARM 8MEQ N17476 002
/BC/ /8MEQ/ /N17476/002/

PRAZEPAM

CAPSULE; ORAL
CENTRAX
> ADD > AB PARKE DAVIS 5MG N18144 001
> ADD > AB 10MG N18144 002
PRAZEPAM
> ADD > AB PHARM BASICS 5MG¤ N70427 001 NOV 06, 1987
> ADD > AB 10MG¤ N70428 001 NOV 06, 1987

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
PREDNISOLONE SODIUM PHOSPHATE
AP STERIS LABS EQ 20MG PHOSPHATE/ML N80517 001
/SOLU-PRED/
/AP/ /STERIS LABS/ /EQ 20MG PHOSPHATE/ML/ /N80517/001/

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE
AT ∂ BARNES HIND EQ 0.9% PHOSPHATE N84168 001
AT ∂ EQ 0.9% PHOSPHATE N84169 001
AT ∂ EQ 0.9% PHOSPHATE N84172 001
AT ∂ MAURRY BIO EQ 0.9% PHOSPHATE N83358 002

PREDNISONE

TABLET; ORAL
PREDNISONE

> ADD >	AB	HEATHER DRUG	5MG		N80320 001
> ADD >	AB		10MG		N84341 001
> ADD >	AB		20MG		N84417 001
> ADD >	AB		20MG		N85543 001
> ADD >	AB		50MG		N86946 001
> DLT >	/BX/		/5MG/		/N80320/001/
> DLT >	/BX/		/10MG/		/N84341/001/
> DLT >	/BX/		/20MG/		/N84417/001/
> DLT >	/BX/		/20MG/		/N85543/001/
> DLT >	/BX/		/50MG/		/N86946/001/
	AB	INTERPHARM	5MG¤		N89597 001 OCT 05, 1987
	AB		10MG¤		N89598 001 OCT 05, 1987
	AB		20MG¤		N89599 001 OCT 05, 1987

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINAMIDE HCL

AP	STERLING DRUG	500MG/ML¤		N89537 001 AUG 25, 1987

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	250MG¤		N89369 001 AUG 14, 1987
AB		500MG¤		N89370 001 JAN 09, 1987
AB		750MG¤		N89371 001 AUG 14, 1987

PROCAN SR

AB	PARKE DAVIS	1GM		N88489 001 JAN 16, 1985

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE

AP	STERIS LABS	EQ 5MG BASE/ML¤		N89530 001 JUL 08, 1987
AP		EQ 5MG BASE/ML¤		N89605 001 JUL 08, 1987
AP		EQ 5MG BASE/ML¤		N89606 001 JUL 08, 1987

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

PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL
PROMETHAZINE HCL

BR	G&W LABS	50MG¤		N87165 001 AUG 14, 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

PROPRANOLOL HYDROCHLORIDE

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
AB	LEMMON	10MG¤	N70232 001	OCT 07, 1987
AB	MATSON LABS	60MG¤	N71791 001	JUL 15, 1987
AB		90MG¤	N71792 001	JUL 15, 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

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL

AP	LYPHOMED	10MG/ML¤	N71188 001	JUL 23, 1987
AP		15MG/ML¤	N71189 001	JUL 23, 1987

SODIUM CHLORIDE

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

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS

>ADD> AP	ABBOTT LABS	50MG/VIAL¤	N71555 001	NOV 16, 1987

>ADD>

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION
HUMATROPE
LILLY

	2MG/VIAL¤	N19640 001	JUN 23, 1987
	5MG/VIAL¤	N19640 004	MAR 08, 1987

SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE

AB	SUPERPHARM	25MG		N89364 001 NOV 07, 1986

STREPTOMYCIN SULFATE

INJECTABLE; INJECTION

STREPTOMYCIN SULFATE

BP	COPANOS INC	EQ 500MG BASE/ML		N60684 001

SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE; UREA

CREAM; VAGINAL

VAGILIA

> ADD > AT	LEMMON	3.7%;2.86%;3.42%;0.64%		N88821 001 NOV 09, 1987

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM

AT	STERIS LABS	30%		N89068 001 MAY 05, 1987

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOPRIM

AP	QUAD PHARMS	80MG/ML;16MG/ML		N71341 001 DEC 29, 1987 : AUG 07, 1987

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

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	INTERPHARM	400MG;80MG		N71299 001 OCT 27, 1987
AB		800MG;160MG		N71300 001 OCT 27, 1987

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

AB	PLANTEX	800MG;160MG		N70037 001 SEP 19, 1985

SULFAMETHOXAZOLE AND TRIMETHOPRIM SINGLE STRENGTH

AB	PLANTEX	400MG;80MG		N70030 001 SEP 19, 1985

UROPLUS DS

AB	SHIONOGI USA	800MG;160MG		N71816 001 SEP 28, 1987

UROPLUS SS

AB	SHIONOGI USA	400MG;80MG		N71815 001 SEP 28, 1987

SULFANILAMIDE

CREAM; VAGINAL

AVC

AT	MERRELL DOW	15%		N06530 003 JAN 27, 1987

VAGITROL

AT	LEMMON	15%		N88718 001 SEP 19, 1985

SUPPOSITORY; VAGINAL

AVC

	MERRELL DOW	1.05GM		N06530 004 JAN 27, 1987

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

AB	MUTUAL PHARM	500MG		N89590 001 OCT 19, 1987
AB	SUPERPHARM	500MG		N89339 001 OCT 26, 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
AH-PYROTEC
AP CIS US N/A¤ N19039 001
JUN 30, 1987

TECHNETIUM TC-99M SULFUR COLLOID KIT

INJECTABLE; INJECTION
/TECHNETIUM TC 99M TSC/
/AP/ /MEDI PHYSICS/ /N/A/ /N17784 001/

SOLUTION; INJECTION, ORAL
TECHNETIUM TC 99M TSC
AP MEDI PHYSICS N/A N17784 001

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
AB PUREPAC PHARM 15MG¤ N71638 001
AUG 07, 1987
AB 30MG¤ N71620 001
AUG 07, 1987

TERAZOSIN HYDROCHLORIDE

TABLET; ORAL
HYTRIN
ABBOTT LABS 1MG¤ N19057 001
AUG 07, 1987
2MG¤ N19057 002
AUG 07, 1987
5MG¤ N19057 003
AUG 07, 1987
∂ 10MG¤ N19057 004
AUG 07, 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

THEOLAIR-SR
BC RIKER LABS 200MG¤ N88369 001
JUL 16, 1987
BC 300MG¤ N88364 001
JUL 16, 1987
250MG¤ N86363 002
JUL 16, 1987
500MG¤ N89132 001
JUL 16, 1987

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

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

	THIORIDAZINE HCL			
> ADD > AA	COPLEY PHARM	30MG/ML		N89602 001 NOV 09, 1987
> ADD > AA		100MG/ML		N89603 001 NOV 09, 1987

THIOTHIXENE

CAPSULE; ORAL

	NAVANE		
AB	ROERIG	1MG	N16584 001
AB		2MG	N16584 002
AB		5MG	N16584 003
AB		10MG	N16584 004
	THIOTHIXENE		
AB	AM THERPTCS	1MG	N71884 001 AUG 12, 1987
AB		2MG	N71885 001 AUG 12, 1987
AB		5MG	N71886 001 AUG 12, 1987
AB		10MG	N71887 001 AUG 12, 1987
AB	CHELSEA LABS	2MG	N71626 001 JUN 25, 1987
AB		5MG	N71627 001 JUN 25, 1987
AB		10MG	N71628 001 JUN 25, 1987
AB	CORD LABS	1MG	N71610 001 JUN 24, 1987
AB		2MG	N71570 001 JUN 24, 1987
AB		5MG	N71529 001 JUN 24, 1987
AB		10MG	N71530 001 JUN 24, 1987

THIOTHIXENE

CAPSULE; ORAL

	THIOTHIXENE		
AB	DANBURY PHARMA	1MG	N70600 001 JUN 05, 1987
AB		2MG	N70601 001 JUN 05, 1987
AB		5MG	N70602 001 JUN 05, 1987
AB		10MG	N70603 001 JUN 05, 1987
AB	MYLAN PHARMS	1MG	N71090 001 JUN 23, 1987
AB		2MG	N71091 001 JUN 23, 1987
AB		5MG	N71092 001 JUN 23, 1987
AB		10MG	N71093 001 JUN 23, 1987

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

	NAVANE		
AA	ROERIG	EQ 5MG BASE/ML	N16758 001
	THIOTHIXENE HCL		
AA	BARRE NATL	EQ 5MG BASE/ML	N70969 001 OCT 16, 1987
AA	COPLEY PHARM	EQ 5MG BASE/ML	N71554 001 OCT 16, 1987
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

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

AB	MUTUAL PHARM	100MG¤	N71357 001 JUL 16, 1987
AB		250MG¤	N71358 001 JUL 16, 1987
AB		500MG¤	N71359 001 JUL 16, 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

TRIAMCINOLONE ACETONIDE

INJECTABLE; INJECTION
TRIAMCINOLONE ACETONIDE

AB	PARNELL PHARM	3MG/ML¤	N19503 001 OCT 16, 1987

PASTE; DENTAL
ORALONE

AT	THAMES PHARMA	0.1%¤	N71383 001 JUL 06, 1987

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
TRIMETHOBENZAMIDE HCL

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

TRIMETHOPRIM

TABLET; ORAL
TRIMETHOPRIM

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

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
SURMONTIL

AB	WYETH LABS	EQ 25MG BASE	N16792 001
AB		EQ 50MG BASE	N16792 002
AB		EQ 100MG BASE	N16792 003 SEP 15, 1982

TRIMIPRAMINE MALEATE

AB	VITARINE	EQ 25MG BASE¤	N71832 001 SEP 10, 1987
AB		EQ 50MG BASE¤	N71833 001 SEP 10, 1987
AB		EQ 100MG BASE¤	N71834 001 SEP 10, 1987

VALPROIC ACID

CAPSULE; ORAL
VALPROIC ACID

AB	FORMUTEC	250MG¤	N70631 001 JUN 11, 1987
AB	SCHERER	250MG¤	N70195 001 JUL 02, 1987

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
LYPHOCIN

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

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
VANCOCIN HCL

AP	LILLY	EQ 500MG BASE/VIAL¤	N62716 001	
			MAR 13, 1987	
> ADD > AP		EQ 500MG BASE/VIAL¤	N62812 001	
> ADD >			NOV 17, 1987	
		EQ 1GM BASE/VIAL¤	N62716 002	
			MAR 13, 1987	
> ADD >		EQ 1GM BASE/VIAL¤	N62812 002	
> ADD >			NOV 17, 1987	
> ADD >		EQ 10GM BASE/VIAL¤	N62812 003	
> ADD >			NOV 17, 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	SOLOPAK LABS	2.5MG/ML¤	N70695 001
			JUL 31, 1987
AP		2.5MG/ML¤	N70696 001
			JUL 31, 1987
AP		2.5MG/ML¤	N70697 001
			JUL 31, 1987
AP	WINTHROP BREON	2.5MG/ML¤	N70577 001
			FEB 02, 1987

TABLET; ORAL
ISOPTIN

> ADD >	KNOLL PHARM	40MG¤	N18593 003
> ADD >			NOV 23, 1987

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VELSAR

AP	ADRIA LABS	10MG/VIAL¤	N89565 001
			AUG 18, 1987

VINBLASTINE SULFATE

AP	BEN VENUE LABS	10MG/VIAL¤	N89395 001
			APR 09, 1987

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

AP	LYPHOMED	1MG/ML¤	N89515 001
			APR 29, 1987
AP	QUAD PHARMS	1MG/ML¤	N89311 001
			MAR 23, 1987

VINCRISTINE SULFATE

INJECTABLE; INJECTION
VINCASAR PFS

AP	ADRIA LABS	1MG/ML¤	N71426 001
			JUL 17, 1987

VINCRISTINE SULFATE

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

WARFARIN POTASSIUM

TABLET; ORAL
ATHROMBIN-K

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

WARFARIN SODIUM

TABLET; ORAL
ATHROMBIN

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

XENON, XE-133

INJECTABLE; INJECTION
XENON XE 133

ə DUPONT DIAG	6.3MCI/ML	N17283 001

XYLOSE

POWDER; ORAL
XYLO-PFAN

AA	ADRIA LABS	25GM/BOT	N17605 001

XYLOSE

POWDER; ORAL
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

(ALL PRODUCTS - SEE INTRODUCTION)

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

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL
ALUMINUM HYDROXIDE AND MAGNESIUM TRISILICATE

>ADD< PENNEX PRODS	80MG;20MG¤	N89449 001 NOV 27, 1987

FOAMCOAT

GUARDIAN DRUG	80MG;20MG¤	N71793 001 SEP 04, 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
>ADD< NASKA PHARMA	500 UNITS/GM¤	N62857 001 NOV 13, 1987

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; TOPICAL
BACITRACIN ZINC-NEOMYCIN SULFATE-POLYMYXIN B SULFATE

NASKA PHARMA	400 UNITS/GM;EQ 3.5MG BASE/GM; 5,000 UNITS/GM¤	N62833 001 NOV 09, 1987

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; TOPICAL
BACITRACIN ZINC-POLYMYXIN B SULFATE

NASKA PHARMA	500 UNITS/GM; 10,000 UNITS/GM¤	N62849 001 NOV 13, 1987

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE

TABLET, CONTROLLED RELEASE; ORAL
BROMATAPP

COPLEY PHARM	12MG;75MG¤	N71099 001 JUL 02, 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

DEXTROMETHORPHAN POLISTIREX

SUSPENSION, CONTROLLED RELEASE; ORAL
>ADD< DELSYM

>ADD< PENNWALT	EQ 30MG HBR/5ML	N18658 001

/DEXTROMETHORPHAN/RESIN/COMPLEX/

/SUSPENSION;/CONTROLLED/RELEASE;/ORAL/
/DELSYM/
/PENNWALT/ /EQ/30MG/HBR/5ML/ /N18658/001/

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

DOXYLAMINE SUCCINATE

TABLET; ORAL
DOXY-SLEEP-AID
PAR PHARM 25MG N70156 001 JUL 02, 1987

IBUPROFEN

CAPSULE; ORAL
MIDOL
STERLING DRUG 200MG N70626 001 SEP 02, 1987
200MG N71002 001 SEP 02, 1987

TABLET; ORAL
ACHES-N-PAIN
LEDERLE LABS 200MG N71065 001 MAY 28, 1987

IBUPRIN
SIDMAK LABS 200MG N71773 001 JUL 16, 1987

IBUPROFEN
CHELSEA LABS 200MG N71765 001 SEP 04, 1987
HALSEY DRUG 200MG N71027 001 SEP 29, 1987
INTERPHARM 200MG N71333 001 FEB 17, 1987
MUTUAL PHARM 200MG N71229 001 APR 01, 1987

IBUPROFEN

TABLET; ORAL
IBUPROFEN
PAR PHARM 200MG N70985 001 OCT 02, 1987
200MG N71575 001 MAY 08, 1987
PRIVATE FMLTNS 200MG N71732 001 SEP 10, 1987
200MG N71735 001 SEP 10, 1987
PUREPAC PHARM 200MG N71664 001 FEB 03, 1987
ZENITH LABS 200MG N71154 001 OCT 27, 1987

MIDOL
STERLING DRUG 200MG N70591 001 SEP 02, 1987
200MG N71001 001 SEP 02, 1987

NEUVIL
LUCHEM PHARMS 200MG N71144 001 JAN 20, 1987

NUPRIN
UPJOHN 200MG N19012 003 JUL 29, 1987

TRENDAR
WHITEHALL LABS 200MG N18989 002 JUL 10, 1986

INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN U
LILLY 40 UNITS/ML N19571 001 JUN 10, 1987
100 UNITS/ML N19571 002 JUN 10, 1987

POVIDONE-IODINE

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

PSEUDOEPHEDRINE POLISTIREX

SUSPENSION, CONTROLLED RELEASE; ORAL

PSEUDO-12		
PENNWALT	EQ 60MG HCL/5ML*	N19401 001 JUN 19, 1987

SODIUM MONOFLUOROPHOSPHATE

PASTE; DENTAL

EXTRA-STRENGTH AIM		
LEVER BROTHERS	1.2%*	N19518 001 JUN 03, 1987

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP

INJECTABLE; INJECTION
NONE
CUTTER BIO N 71497

PENTASTARCH 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
PENTASPAN(R)
DUPONT CRI CARE 10GM/100ML;0.9GM/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 20, 1987	ODE APR 20, 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 2MG/VIAL	HUMATROPE INJECTABLE; INJECTION	LILLY	19640 001 JUN 23, 1987	ODE MAR 08, 1994
SOMATROPIN, BIOSYNTHETIC 5MG/VIAL	HUMATROPE INJECTABLE; INJECTION	LILLY	19640 004 MAR 08, 1987	ODE MAR 08, 1994
UROFOLLITROPIN 75IU/AMP	METRODIN INJECTABLE; INJECTION	SERONO LABS	19415 002 SEP 18, 1986	ODE SEP 18, 1993
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 NOVEMBER 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 (DOSAGE FORM)	DATE	REVISED DATE
ALBUTEROL (TABLET)	MAY 05, 1987	
AMOXAPINE (TABLET)	SEP 10, 1987	
AMOXICILLIN (CAPSULE AND TABLET)	AUG 18, 1987	
CARBAMAZEPINE (TABLET)	DEC 05, 1984	SEP 30, 1987
CEPHALEXIN (CAPSULE AND TABLET)	AUG 13, 1986	MAR 19, 1987
CLORAZEPATE DIPOTASSIUM	MAR 10, 1986	FEB 17, 1987
DESIPRAMINE HYDROCHLORIDE (TABLET)	APR 28, 1987	SEP 22, 1987
DIPYRIDAMOLE (TABLET)	JUL 05, 1983	SEP 25, 1987
DISSOLUTION TESTING (GENERAL)	APR 01, 1978*	
FENOPROFEN (CAPSULE AND TABLET)	AUG 27, 1987	SEP 25, 1987
HALOPERIDOL (TABLET)	APR 30, 1987	
HYDROCHLOROTHIAZIDE (TABLET)	JUL 25, 1983	SEP 28, 1987
HYDROXYZINE PAMOATE (CAPSULE)	JUL 26, 1983	SEP 28, 1987
ISOSORBIDE DINITRATE (CHEWABLE TABLET, ORAL TABLET, AND SUBLINGUAL TABLET)	JUN 04, 1985	SEP 22, 1987

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

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

NAME OF DRUG (DOSAGE FORM)	DATE	REVISED DATE
LEUCOVORIN CALCIUM (TABLET)	APR 28, 1987	
LORAZEPAM (TABLET)	DEC 03, 1984	SEP 16, 1987
LOXAPINE SUCCINATE (CAPSULE)	SEP 10, 1987	
MAPROTILINE HYDROCHLORIDE (TABLET)	AUG 27, 1987	
MEDROXYPROGESTERONE ACETATE (TABLET)	DEC 24, 1986	SEP 17, 1987
MEGESTROL ACETATE (TABLET)	AUG 17, 1987	
NAFCILLIN SODIUM (CAPSULE AND TABLET)	SEP 10, 1987	
NALIDIXIC ACID (TABLET)	AUG 19, 1987	
OXYPHENBUTAZONE (TABLET)	JUL 26, 1983	SEP 28, 1987
PERPHENAZINE (TABLET)	AUG 27, 1987	
PERPHENAZINE AMITRIPTYLINE (TABLET)	AUG 27, 1987	
PHENYLBUTAZONE (CAPSULE AND TABLET)	JUL 26, 1983	SEP 28, 1987
POTASSIUM CHLORIDE (CAPSULE, SLOW RELEASE AND TABLET, SLOW RELEASE)	JAN 17, 1987	
PROCAINAMIDE (TABLET)	JUL 25, 1983	SEP 28, 1987
QUINIDINE GLUCONATE (TABLET, CONTROLLED RELEASE)	JUN 15, 1981	SEP 22, 1987
RITODRINE HYDROCHLORIDE (TABLET)	AUG 27, 1987	
SULFASALAZINE (TABLET)	OCT 08, 1987	
SULFINPYRAZONE (CAPSULE AND TABLET)	JUL 15, 1983	SEP 25, 1987
SULINDAC (TABLET)	SEP 28, 1987	
TRIMIPRAMINE MALEATE (CAPSULE)	NOV 03, 1986	AUG 18, 1987

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; BUTALBITAL; CAFFEINE TABLET; ORAL	500MG 50MG 40MG	86 P-0514/CP	FOREST LABS	NEW STRENGTH	APPROVED JUL 15, 1987
ACETAMINOPHEN; CODEINE PHOSPHATE SYRUP; ORAL	160MG/5ML 6MG/5ML	87 P-0323/CP	KLEINFELD, KAPLAN AND BECKER	NEW DOSAGE FORM NEW STRENGTH	APPROVED NOV 04, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 2.5MG	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 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
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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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
ACETAMINOPHEN; HYDROCODONE BITARTRATE ELIXIR; ORAL	500MG/15ML 7.5MG/15ML	85 P-0439/ CP0003	RUSS PHARMS	NEW DOSAGE FORM NEW STRENGTH	APPROVED APR 01, 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	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 TABLET; ORAL	500MG 10MG	87 P-0170/CP	LUCHEM PHARM	NEW STRENGTH	APPROVED JUL 07, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE CAPSULE; 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	650MG 7.5MG	85 P-0390/CP	UAD LABS	NEW STRENGTH NEW DOSAGE FORM	APPROVED MAR 17, 1987
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	750MG 7.5MG	85 P-0169/PRC*	KNOLL PHARM	NEW STRENGTH	APPROVED MAR 13, 1987
AMINOPHYLLINE INJECTABLE; INJECTION	10MG/ML (10ML/VIAL)	87 P-0103/CP	LYPHOMED	NEW STRENGTH	APPROVED JUL 07, 1987
ASPIRIN; HYDROCODONE BITARTRATE TABLET; ORAL	500MG 7.5MG	87 P-0100/CP	KING AND SPAULDING	NEW STRENGTH	APPROVED APR 24, 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
BRETYLIUM TOSYLATE INJECTABLE; INJECTION	200MG/ML (5ML/CONTAINER)	87 P-0228/CP	ASTRA PHARM PRODS	NEW STRENGTH	APPROVED OCT 06, 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
BRETYLIUM TOSYLATE IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (100ML/CONTAINER)	87 P-0128/CP	LYPHOMED	NEW STRENGTH	APPROVED JUL 22, 1987
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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CHOLESTYRAMINE GEL; ORAL	EQ 4GM RESIN/ CONTAINER	87 P-0301/CP	CIBA PHARM	NEW DOSAGE FORM	APPROVED NOV 04, 1987
CHOLESTYRAMINE TABLET; ORAL	EQ 800MG RESIN	86 P-0475/CP	BRISTOL MYERS	NEW DOSAGE FORM NEW STRENGTH	APPROVED JAN 30, 1987
CISPLATIN INJECTABLE; INJECTION	20MG/VIAL	87 P-0291/CP	LYPHOMED	NEW STRENGTH	APPROVED NOV 03, 1987
CISPLATIN INJECTABLE; INJECTION	1MG/ML (100ML/VIAL) (500ML/VIAL)	87 P-0130/CP	TRAVENOL LABS	NEW DOSAGE FORM NEW STRENGTH	APPROVED OCT 06, 1987
CLEMASTINE FUMARATE; PSEUDOEPHEDRINE HYDROCHLORIDE TABLET, CONTROLLED RELEASE; ORAL	EQ 1MG BASE 120MG	87 P-0314/CP	DORSEY LABS/SANDOZ	NEW COMBINATION	APPROVED NOV 03, 1987
CYTARABINE INJECTABLE; INJECTION	1,000MG/VIAL	86 P-0313/CP	QUAD PHARMS	NEW STRENGTH	APPROVED MAY 07, 1987

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CYTARABINE INJECTABLE; INJECTION	20MG/ML (50ML/CONTAINER)	86 P-0428/ CP0002	ADRIA LABS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAY 07, 1987
DESONIDE LOTION; TOPICAL	0.05%	87 P-0105/CP	OWEN LABS	NEW DOSAGE FORM	APPROVED SEP 10, 1987
DEXBROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE TABLET, CONTROLLED RELEASE; ORAL	6MG 75MG	87 P-0265/CP	BOCK PHARMA	NEW COMBINATION NEW DOSAGE FORM	APPROVED NOV 04, 1987
DEXTROMETHORPHAN POLISTIREX SUSPENSION, CONTROLLED RELEASE; ORAL	EQ 15MG HBR/5ML	87 P-0088/CP	KING AND SPAULDING	NEW STRENGTH	APPROVED APR 27, 1987
DIAZOXIDE INJECTABLE; INJECTION	15MG/ML (10ML/CONTAINER)	87 P-0061/CP	LYPHOMED	NEW STRENGTH	APPROVED APR 30, 1987

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
FENOPROFEN CALCIUM TABLET; ORAL	EQ 200MG BASE EQ 300MG BASE	87 P-0133/CP	BARR LABS	NEW STRENGTH	APPROVED AUG 04, 1987
FLUOCINONIDE LOTION; TOPICAL	0.05%	87 P-0004/CP	RICHARD HAMER ASSOC	NEW DOSAGE FORM	APPROVED SEP 10, 1987
FLUOROURACIL INJECTABLE; INJECTION	50MG/ML (50ML/VIAL)	86 P-0490/CP	ADRIA LABS	NEW STRENGTH	APPROVED JAN 09, 1987
IBUPROFEN SOFT GELATIN CAPUSLE; ORAL	200MG	87 P-0232/CP	SIDMAK LABS	NEW DOSAGE FORM	APPROVED OCT 06, 1987
IBUPROFEN SOFT GELATIN CAPUSLE; ORAL	800MG	87 P-0242/CP	SIDMAK LABS	NEW DOSAGE FORM	APPROVED OCT 06, 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 5MG BASE/ML (10ML/VIAL)	86 P-0241/CP	QUAD PHARMS	NEW STRENGTH	APPROVED JUL 28, 1987

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 5MG BASE/ML (20ML/VIAL)	86 P-0241/CP	QUAD PHARMS	NEW STRENGTH	APPROVED JUL 28, 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
LOPERAMIDE HYDROCHLORIDE TABLET; ORAL	2MG	87 P-0268/CP	KROSS	NEW DOSAGE FORM	APPROVED OCT 06, 1987
LORAZEPAM SOFT GELATIN CAPSULE; ORAL	0.5MG 1MG 2MG	87 P-0037/CP	APPLIED LABS	NEW DOSAGE FORM	APPROVED MAR 10, 1987
LORAZEPAM TABLET; ORAL	0.5MG 1MG 2MG	85 P-0515/CP	WYETH INC	NEW DOSAGE FORM	APPROVED FEB 25, 1986
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
MORPHINE SULFATE INJECTABLE; INJECTION	0.5MG/ML (2ML/AMP)	87 P-0106/CP	ASTRA PHARM PRODS	NEW STRENGTH	APPROVED JUL 15, 1987
MORPHINE SULFATE INJECTABLE; INJECTION	1MG/ML (2ML/AMP)	87 P-0106/CP	ASTRA PHARM PRODS	NEW STRENGTH	APPROVED JUL 15, 1987
NITROGLYCERIN OINTMENT; TOPICAL	4%	87 P-0184/CP	FOREST LABS	NEW STRENGTH	APPROVED SEP 15, 1987
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	0.5MG/ML (100ML/CONTAINER)	86 P-0099/ CP0004	ABBOTT LABS	NEW STRENGTH	APPROVED FEB 02, 1987
OXAZEPAM CAPSULE; ORAL	10MG 15MG 30MG	87 P-0157/CP	BARR LABS	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUL 17, 1987
OXAZEPAM TABLET; ORAL	15MG 30MG	85 P-0516/CP	WYETH INC	NEW DOSAGE FORM	APPROVED FEB 25, 1986

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
PREDNISOLONE SODIUM PHOSPHATE SOLUTION; ORAL	EQ 15MG BASE/5ML	87 P-0235/CP	FISONS	NEW STRENGTH	APPROVED NOV 04, 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
PSEUDOEPHEDRINE HYDROCHLORIDE TABLET, CONTROLLED RELEASE; ORAL	120MG	87 P-0297/CP	HLTH PLCY NTWK	NEW DOSAGE FORM	APPROVED NOV 03, 1987
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE TABLET, CONTROLLED RELEASE; ORAL	120MG 5MG	87 P-0296/CP	HLTH PLCY NTWK	NEW DOSAGE FORM	APPROVED NOV 03, 1987

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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	NEW STRENGTH	APPROVED MAR 10, 1987
TRIAMCINOLONE ACETONIDE LOTION; TOPICAL	0.5%	87 P-0019/CP	RICHARD HAMER ASSOC	NEW STRENGTH	APPROVED SEP 11, 1987
VERAPAMIL HYDROCHLORIDE SOLUTION; ORAL	40MG/5ML 80MG/5ML	87 P-0101/CP	MY K LABS	NEW DOSAGE FORM NEW STRENGTH	APPROVED SEP 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
VINBLASTINE SULFATE INJECTABLE; INJECTION	1MG/ML (30ML/VIAL)	87 P-0211/CP	LYPHOMED	NEW STRENGTH	APPROVED JUL 28, 1987
XENON-133 INJECTABLE; INJECTION	60MCI/VIAL 150MCI/VIAL	86 P-0342/CP	MEDI NUCLR	NEW STRENGTH	APPROVED SEP 11, 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 PHARMS	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
I-68	RELIEF OF MILD TO MODERATE PAIN
I-69	TREATMENT OF CUTANEOUS CANDIDIASIS
I-70	URINARY TRACT INFECTION (UTI) PREVENTION FOR PERIODS UP TO FIVE MONTHS IN WOMEN WITH A HISTORY OF RECURRENT UTI'S
I-71	SEBORRHEIC DERMATITIS

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	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
18917 001	ACEBUTOLOL HYDROCHLORIDE; SECTRAL	3857952	DEC 31, 1993	U-4		
18917 003	ACEBUTOLOL HYDROCHLORIDE; SECTRAL	3857952	DEC 31, 1993	U-4		
19112 001	ALBUTEROL SULFATE; VENTOLIN	3705233	DEC 05, 1989			
		3644353	FEB 22, 1989			
19112 002	ALBUTEROL SULFATE; VENTOLIN	3705233	DEC 05, 1989			
		3644353	FEB 22, 1989			
19243 001	ALBUTEROL SULFATE; PROVENTIL	3705233	DEC 05, 1989			
		3644353	FEB 22, 1989		NDF	JAN 14, 1990
19243 002	ALBUTEROL SULFATE; PROVENTIL	3705233	DEC 05, 1989			
		3644353	FEB 22, 1989		NDF	JAN 14, 1990
19383 001	ALBUTEROL SULFATE; PROVENTIL	3705233	DEC 05, 1989			
		3644353	FEB 22, 1989		NDF	JUL 13, 1990
19621 001	ALBUTEROL SULFATE; VENTOLIN	3705233	DEC 05, 1989			
		3644353	FEB 22, 1989			
19353 001	ALFENTANIL HYDROCHLORIDE; ALFENTA	4167574	SEP 11, 1996		NCE	DEC 29, 1991
18700 001	AMRINONE LACTATE; INOCOR	4072746	FEB 07, 1995	U-11	NCE	JUL 31, 1994
19389 001	BECLOMETHASONE DIPROPIONATE; BECONASE AQ				NP	JUL 27, 1990
19408 001	BETAMETHASONE DIPROPIONATE; DIPROLENE	4489070	DEC 18, 2001			
		4482539	NOV 13, 2001			
19555 001	BETAMETHASONE DIPROPIONATE; DIPROLENE AF	4489071	DEC 18, 2001			
19270 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC	4252984	JUL 31, 1999		NCE	AUG 30, 1990
18770 001	BITOLTEROL MESYLATE; TORNALATE	4336400	JUN 22, 1999	U-10		
		4336400	JUN 22, 1999	U-9		
				U-10		
18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994			
18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994			
18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994			
18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	JAN 08, 1999			
18731 001	*BUSPIRONE HYDROCHLORIDE; BUSPAR*	*4182763*	*JAN 08, 1997*			
18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	JAN 08, 1999			
18731 002	*BUSPIRONE HYDROCHLORIDE; BUSPAR*	*4182763*	*JAN 08, 1997*			
19215 001	BUTOCONAZOLE NITRATE; FEMSTAT	4078071	MAR 07, 1997		NCE	NOV 25, 1990
18470 001	CALCITONIN, HUMAN; CIBACALCIN	RE32347	JUN 30, 1998		NCE	OCT 31, 1991
					ODE	OCT 31, 1993
18067 001	CINOXACIN; CINOBAC	3669965	JUN 13, 1989		I-70	OCT 28, 1990
19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO				NCE	OCT 22, 1992
19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO				NCE	OCT 22, 1992
19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO				NCE	OCT 22, 1992
18057 001	CISPLATIN; PLATINOL	4177263	DEC 04, 1996			
18057 002	CISPLATIN; PLATINOL	4177263	DEC 04, 1996			
18057 003	CISPLATIN; PLATINOL-AQ	4177263	DEC 04, 1996			

APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19322 001	CLOBETASOL PROPIONATE; TEMOVATE	3721687	MAR 20, 1992		NCE	DEC 27, 1990
19323 001	CLOBETASOL PROPIONATE; TEMOVATE	3721687	MAR 20, 1992		NCE	DEC 27, 1990
12141 001	CYCLOPHOSPHAMIDE; CYTOXAN				I-63	APR 29, 1990
12141 002	CYCLOPHOSPHAMIDE; CYTOXAN				I-63	APR 29, 1990
12142 001	CYCLOPHOSPHAMIDE; CYTOXAN				I-63	APR 29, 1990
12142 002	CYCLOPHOSPHAMIDE; CYTOXAN				I-63	APR 29, 1990
12142 003	CYCLOPHOSPHAMIDE; CYTOXAN				I-63	APR 29, 1990
12142 004	CYCLOPHOSPHAMIDE; CYTOXAN				I-63	APR 29, 1990
12142 005	CYCLOPHOSPHAMIDE; CYTOXAN				I-63	APR 29, 1990
12142 006	CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN	4537883	AUG 27, 2002		I-63	APR 29, 1990
12142 007	CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN	4537883	AUG 27, 2002		I-63	APR 29, 1990
12142 008	CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN	4537883	AUG 27, 2002		I-63	APR 29, 1990
12142 009	CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN	4537883	AUG 27, 2002		I-63	APR 29, 1990
12142 010	CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN	4537883	AUG 27, 2002		I-63	APR 29, 1990
18885 002	DIHYDROERGOTAMINE MESYLATE; EMBOLEX	4402949	SEP 06, 2000		I-67	JUN 22, 1990
12836 004	DIPYRIDAMOLE; PERSANTINE				I-49	DEC 22, 1989
12836 005	DIPYRIDAMOLE; PERSANTINE				I-49	DEC 22, 1989
17820 002	DOBUTAMINE HYDROCHLORIDE; DOBUTREX	3987200	OCT 19, 1993	U-11		
19386 002	ESMOLOL HYDROCHLORIDE; BREVIBLOC	4593119	JUN 03, 2003		NCE	DEC 31, 1991
16672 001	ETHINYL ESTRADIOL; OVRAL	4387103	JUN 07, 2000	U-16		
		3666858	MAY 30, 1989	U-1		
		3666858	MAY 30, 1989	U-2		
		3666858	MAY 30, 1989	U-3		
16806 001	ETHINYL ESTRADIOL; OVRAL-28	3666858	MAY 30, 1989	U-1		
		3666858	MAY 30, 1989	U-2		
		3666858	MAY 30, 1989	U-3		
17612 001	ETHINYL ESTRADIOL; LO/OVRAL	3666858	MAY 30, 1989	U-1		
		3666858	MAY 30, 1989	U-2		
		3666858	MAY 30, 1989	U-3		
17802 001	ETHINYL ESTRADIOL; LO/OVRAL-28	3666858	MAY 30, 1989	U-1		
		3666858	MAY 30, 1989	U-2		
		3666858	MAY 30, 1989	U-3		
18668 001	ETHINYL ESTRADIOL; NORDETTE-21	3666858	MAY 30, 1989	U-1		
		3666858	MAY 30, 1989	U-2		
		3666858	MAY 30, 1989	U-3		
18782 001	ETHINYL ESTRADIOL; NORDETTE-28	3666858	MAY 30, 1989	U-1		
		3666858	MAY 30, 1989	U-2		
		3666858	MAY 30, 1989	U-3		
19190 001	ETHINYL ESTRADIOL; TRIPHASIL-28	3957982	MAY 18, 1993	U-1		
		3666858	MAY 30, 1989	U-1		
		3666858	MAY 30, 1989	U-2		
		3666858	MAY 30, 1989	U-3		

APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19192 001	ETHINYL ESTRADIOL; TRIPHASIL-21	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	ETIDRONATE DISODIUM; DIDRONEL	4254114	MAR 03, 1998			
		4216211	AUG 05, 1997			
		4137309	JAN 30, 1996		ODE	APR 20, 1994
		3683080	AUG 08, 1989		NDF	APR 20, 1990
19369 001	ETRETINATE; TEGISON	4215215	JUL 29, 1999		NCE	SEP 30, 1991
19369 001	ETRETINATE; TEGISON	4215215	JUL 29, 1997		NCE	SEP 30, 1991
19369 002	ETRETINATE; TEGISON	4215215	JUL 29, 1999		NCE	SEP 30, 1991
19369 002	ETRETINATE; TEGISON	4215215	JUL 29, 1997		NCE	SEP 30, 1991
19462 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		NCE	OCT 15, 1991
19462 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 1998		NCE	OCT 15, 1991
19462 002	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		NCE	OCT 15, 1991
19462 002	FAMOTIDINE; PEPCID	4283408	AUG 11, 1998		NCE	OCT 15, 1991
19510 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		NCE	OCT 15, 1991
19510 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 1998		NCE	OCT 15, 1991
19527 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		NCE	OCT 15, 1991
19527 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 1998		NCE	OCT 15, 1991
18830 001	FLECAINIDE ACETATE; TAMBOCOR	4005209	JAN 25, 1996			
18830 002	FLECAINIDE ACETATE; TAMBOCOR	4005209	JAN 25, 1996			
19415 002	FLUMAZENIL; METRODIN				NE	SEP 18, 1989
19404 001	FLURBIPROFEN SODIUM; OCUFEN	3793457	FEB 19, 1991			
		3755427	AUG 28, 1990		NCE	DEC 31, 1991
18123 001	GONADORELIN HYDROCHLORIDE; FACTREL	4110438	AUG 29, 1995	U-14		
		3947569	MAR 30, 1993	U-15		
18123 002	GONADORELIN HYDROCHLORIDE; FACTREL	4110438	AUG 29, 1995	U-14		
		3947569	MAR 30, 1993	U-15		
18123 003	GONADORELIN HYDROCHLORIDE; FACTREL	4110438	AUG 29, 1995	U-14		
		3947569	MAR 30, 1993	U-15		
18587 001	GUANABENZ ACETATE; WYTENSIN	3658993	APR 25, 1989	U-5	NCE	SEP 07, 1992
18587 002	GUANABENZ ACETATE; WYTENSIN	3658993	APR 25, 1989	U-5	NCE	SEP 07, 1992
18587 003	GUANABENZ ACETATE; WYTENSIN	3658993	APR 25, 1989	U-5	NCE	SEP 07, 1992
18872 001	HYDROCHLOROTHIAZIDE; VISKAZIDE				NCE	SEP 03, 1992
18872 002	HYDROCHLOROTHIAZIDE; VISKAZIDE				NCE	SEP 03, 1992
19046 001	HYDROCHLOROTHIAZIDE; NORMOZIDE	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NC	APR 06, 1990
19046 002	HYDROCHLOROTHIAZIDE; NORMOZIDE	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NC	APR 06, 1990
19046 003	HYDROCHLOROTHIAZIDE; NORMOZIDE	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NC	APR 06, 1990
19046 004	HYDROCHLOROTHIAZIDE; NORMOZIDE	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NC	APR 06, 1990

APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19174 001	HYDROCHLOROTHIAZIDE; TRANDATE-HCT	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NC	APR 10, 1990
19174 002	HYDROCHLOROTHIAZIDE; TRANDATE-HCT	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NC	APR 10, 1990
19174 003	HYDROCHLOROTHIAZIDE; TRANDATE-HCT	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NC	APR 10, 1990
19174 004	HYDROCHLOROTHIAZIDE; TRANDATE-HCT	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NC	APR 10, 1990
19571 001	INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN; HUMULIN U				NP	JUN 10, 1990
19571 002	INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN; HUMULIN U				NP	JUN 10, 1990
18956 001	IOHEXOL; OMNIPAQUE 180	4396597	JUL 14, 1998		I-65	MAY 12, 1990
		4250113	DEC 26, 1999		NCE	DEC 26, 1990
18956 002	IOHEXOL; OMNIPAQUE 240	4396597	JUL 14, 1998		I-65	MAY 12, 1990
		4250113	DEC 26, 1999		NCE	DEC 26, 1990
18956 003	IOHEXOL; OMNIPAQUE 300	4396597	JUL 14, 1998		I-65	MAY 12, 1990
		4250113	DEC 26, 1999		NCE	DEC 26, 1990
18956 004	IOHEXOL; OMNIPAQUE 350	4396597	JUL 14, 1998		I-65	MAY 12, 1990
		4250113	DEC 26, 1999		NCE	DEC 26, 1990
18735 001	IOPAMIDOL; ISOVUE 200	4001323	JAN 04, 1996		NCE	DEC 31, 1990
					NR	JUL 07, 1990
18735 002	IOPAMIDOL; ISOVUE-300	4001323	JAN 04, 1996		I-57	JUL 07, 1990
18735 003	IOPAMIDOL; ISOVUE-370	4001323	JAN 04, 1996		NCE	DEC 31, 1990
18735 004	IOPAMIDOL; ISOVUE-M 300	4001323	JAN 04, 1996		NCE	DEC 31, 1990
13295 002	IOTHALAMATE MEGLUMINE; CONRAY-43				NCE	DEC 31, 1990
18905 002	IOXAGLATE MEGLUMINE; HEXABRIX	4094966	JUN 13, 1995		I-54	DEC 18, 1989
		4065554	DEC 27, 1994		I-54	OCT 22, 1989
		4065553	DEC 27, 1994		I-36	OCT 22, 1989
		4014986	MAR 29, 1996		I-6	OCT 22, 1989
					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
19084 001	KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999		I-69	SEP 25, 1990
					I-71	OCT 22, 1990
19576 001	KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999		NDF	DEC 31, 1988
					I-69	SEP 25, 1990
19648 001	KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999		I-71	OCT 22, 1990
					NDF	DEC 31, 1988
					I-69	SEP 25, 1990
					I-71	OCT 22, 1990
					NDF	DEC 31, 1988

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
18754 001	KETOPROFEN; ORUDIS	3641127	FEB 08, 1991		NCE	JAN 09, 1991
					I-2	JUL 31, 1990
					I-68	JUL 31, 1990
18754 002	KETOPROFEN; ORUDIS	3641127	FEB 08, 1991		NCE	JAN 09, 1991
					I-2	JUL 31, 1990
					I-68	JUL 31, 1990
18754 003	KETOPROFEN; ORUDIS	3641127	FEB 08, 1991		NCE	JAN 09, 1991
					I-2	JUL 31, 1990
					I-68	JUL 31, 1990
18687 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4066755	JAN 03, 1995			
		4012444	MAR 15, 1994		NCE	AUG 01, 1994
		4005063	JAN 25, 1996		NCE	APR 09, 1990
		4231938	NOV 04, 1997		NCE	AUG 31, 1992
19010 001	LEUPROLIDE ACETATE; LUPRON	3497599	JAN 26, 1988	U-12		
		4137300	JAN 30, 1996		NCE	APR 30, 1992
19643 003	LOVASTATIN; MEVACOR	4536386	AUG 20, 2002	U-13		
16763 001	MAFENIDE ACETATE; SULFAMYLON	4536386	AUG 20, 2002	U-13	I-66	MAY 28, 1990
					NS	MAY 28, 1990
18029 001	METHYLPHENIDATE HYDROCHLORIDE; RITALIN-SR	4517179	MAY 14, 2002		NS	OCT 30, 1990
17862 001	METOCLOPRAMIDE HYDROCHLORIDE; REGLAN	3998790	DEC 21, 1993		I-64	JUN 27, 1989
17862 004	METOCLOPRAMIDE HYDROCHLORIDE; REGLAN	3998790	DEC 21, 1993		I-64	JUN 27, 1989
19532 001	METOLAZONE; MICROX	3954872	MAY 04, 1995		NCE	DEC 30, 1990
17963 001	METOPROLOL TARTRATE; LOPRESSOR	3954872	MAY 04, 1995		NCE	DEC 30, 1990
17963 002	METOPROLOL TARTRATE; LOPRESSOR	3954872	MAY 04, 1995		NCE	DEC 30, 1990
18873 002	MEXILETINE HYDROCHLORIDE; MEXITIL	4280957	JUL 28, 1998		NCE	DEC 20, 1990
18873 003	MEXILETINE HYDROCHLORIDE; MEXITIL	4472393	SEP 18, 2001		NCE	APR 30, 1992
18873 004	MEXILETINE HYDROCHLORIDE; MEXITIL	4472393	SEP 18, 2001		NCE	APR 30, 1992
18654 002	MIDAZOLAM HYDROCHLORIDE; VERSED				NDF	MAY 29, 1990
19543 001	MOMETASONE FUROATE; ELOCON	4087547	MAY 02, 1995	U-8		
19625 001	MOMETASONE FUROATE; ELOCON	4087545	MAY 02, 1995	U-7		
19516 001	MORPHINE SULFATE; MS CONTIN	3928598	DEC 23, 1992	U-6		
18677 001	NABILONE; CESAMET	3920809	NOV 18, 1992		NCE	DEC 26, 1990
		3998966	DEC 21, 1993		I-62	MAR 23, 1990
17581 002	NAPROXEN; NAPROSYN	3904682	SEP 09, 1992		D-13	MAR 23, 1990
		3998966	DEC 21, 1993		I-62	MAR 23, 1990
17581 003	NAPROXEN; NAPROSYN	3904682	SEP 09, 1992		D-13	MAR 23, 1990
		3998966	DEC 21, 1993		I-62	MAR 23, 1990
17581 004	NAPROXEN; NAPROSYN	3904682	SEP 09, 1992		D-13	MAR 23, 1990
		4009197	SEP 09, 1992			
18965 001	NAPROXEN; NAPROSYN	4001301	SEP 09, 1992			
		3998966	DEC 21, 1993			
		3904682	SEP 09, 1992		NDF	MAR 23, 1990

	APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	18164 003	NAPROXEN SODIUM; ANAPROX	4009197	SEP 09, 1992			
			4001301	SEP 09, 1992			
	19384 002	NORFLOXACIN; NOROXIN	3998966	DEC 21, 1993		I-62	MAR 23, 1990
			4639458	JAN 27, 2004			
	17031 001	NORGESTREL; OVRETTE	4146719	MAR 27, 1998		NCE	OCT 31, 1991
			3666858	MAY 30, 1989	U-1		
			3666858	MAY 30, 1989	U-2		
			3666858	MAY 30, 1989	U-3		
	15539 002	OXAZEPAM; SERAX	4620974	NOV 04, 2003			
	15539 004	OXAZEPAM; SERAX	4620974	NOV 04, 2003			
	15539 006	OXAZEPAM; SERAX	4620974	NOV 04, 2003			
	19435 001	PERMETHRIN; NIX	4024163	MAY 17, 1996		NCE	MAR 31, 1991
	18553 004	PROPRANOLOL HYDROCHLORIDE; INDERAL LA	4138475	FEB 06, 1996			
	19536 001	PROPRANOLOL HYDROCHLORIDE; INDERAL	4600708	JUL 15, 2003		D-7	OCT 31, 1989
	18708 003	QUAZEPAM; DORMALIN	3920818	NOV 18, 1992			
	18859 001	RIBAVIRIN; VIRAZOLE	3845039	OCT 29, 1991		NCE	DEC 27, 1990
	19518 001	SODIUM MONOFLUOROPHOSPHATE; EXTRA-STRENGTH AIM	4211771	JUL 08, 1999		NCE	DEC 31, 1990
	19518 002	SODIUM MONOFLUOROPHOSPHATE; EXTRA-STRENGTH AIM				NS	AUG 06, 1989
	19107 001	SOMATREM; PROTROPIN				NS	AUG 06, 1989
	19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE	4658021	APR 14, 2004		NCE	OCT 17, 1990
	19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				ODE	MAR 08, 1994
	18217 001	SUPROFEN; SUPROL				ODE	MAR 08, 1994
	18963 001	TECHNETIUM TC-99M MEBROFENIN KIT; CHOLETEC	4035376	JUL 12, 1996		NCE	DEC 24, 1990
	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	4418208	NOV 29, 2000		NCE	JAN 21, 1992
	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN				NCE	AUG 07, 1992
	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN				NCE	AUG 07, 1992
	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN				NCE	AUG 07, 1992
	18682 001	TIOCONAZOLE; TROSYD				NCE	AUG 07, 1992
	19355 001	TIOCONAZOLE; VAGISTAT	4661493	APR 28, 2004	U-17		
	19503 001	TRIAMCINOLONE ACETONIDE; TRIAMCINOLONE ACETONIDE	4661493	APR 28, 2004	U-17		
>ADD>	19415 002	UROFOLLITROPIN; METRODIN				NS	OCT 16, 1990
>ADD>	18593 003	VERAPAMIL HYDROCHLORIDE; ISOPTIN				ODE	SEP 18, 1993
>ADD>						I-50	DEC 16, 1989
	14103 003	VINCRISTINE SULFATE; ONCOVIN				I-51	DEC 16, 1989
	19655 001	ZIDOVUDINE; RETROVIR	4619935	OCT 28, 2003			
						ODE	MAR 19, 1994
						NCE	MAR 19, 1992

*U.S. GOVERNMENT PRINTING OFFICE:1988-201-867:60004

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