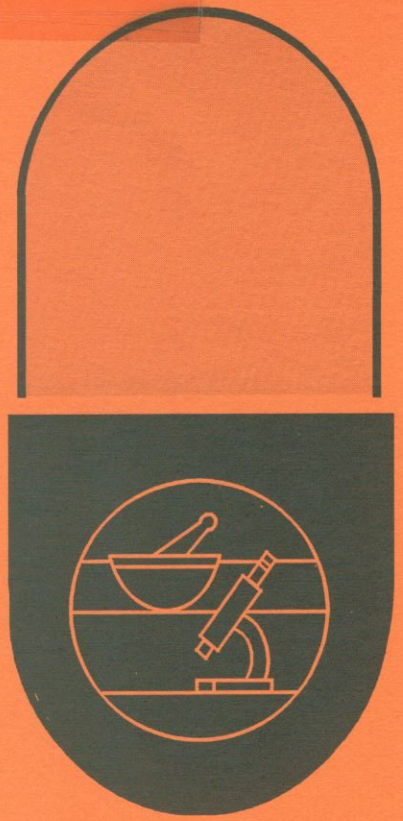
CUMULATIVE
SUPPLEMENT 5
JAN'96-MAY'96



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DRUG INFORMATION RESOURCES

1996

Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

Cumulative Supplement 5

MAY 1996

CONTENTS

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

CUMULATIVE SUPPLEMENT 5
MAY 1996

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, 16th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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 with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research 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. Also shown is the application number and product number (FDA's internal file number) for reference purposes. 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 in the Patent and Exclusivity Information Addendum for an explanation of all codes and 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 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.

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 shaded print. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the shaded print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy 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 16th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 17th Edition.

1.2 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 07, 1984 (49 FR 35428)
Nitroglycerin (film, extended release;transdermal*)	JUL 15, 1993 (58 FR 38129)
Nitroglycerin (tablet, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 05, 1985 (50 FR 27688)

*The Federal Register of July 15, 1993 (58 FR 38129) announced that the FDA was revoking the temporary exemption for nitroglycerin in a transdermal delivery system. Marketing of a drug product that is the subject of a conditionally approved ANDA may continue by meeting the requirements listed in the Federal Register. Firms wishing to submit a new ANDA before a drug product is approved (NDA or ANDA) and appears in the List should submit a 505(b)(2) application following the directions contained in the Federal Register. Nitro-Dur has been selected as the reference listed drug. The preamble to the final rule (57 FR 17958) states if there are multiple NDA's, the reference listed drug generally will be the market leader. This is the basis upon which Nitro-Dur was selected. In addition, the preamble states that, in multiple NDA situations, a product not designated as the reference listed drug and not shown to be bioequivalent to the reference listed drug may be shielded from generic competition. This is the case with Summit's Transderm-Nitro. The Office of Generic Drugs (OGD) has been requested to have a second listed drug as provided for in the Final Rule. OGD has granted this request. Therefore, at the time that Schering's and Summit's supplements are fully approved and their products are entered into the List, we will have two reference listed drugs for the nitroglycerin transdermal systems. Firms may, therefore, elect to conduct bioequivalence studies against either of these products. It is conceivable that a non-referenced listed drug may be fully approved and appear in the List; in this case, the Agency's referenced listed drug will not change and a 505(b)(2) application will be appropriate until the reference listed drugs are fully approved. Once they are fully approved, a 505(j) application will be the appropriate mechanism for an ANDA submission.

1.3 CHANGE OF A THERAPEUTIC EQUIVALENT CODE FOR A DRUG ENTITY

Propantheline Bromide

The purpose of this notice is to advise you that the Agency is considering changing the therapeutic equivalence code for propantheline bromide tablets (PB tablets) as shown in the Agency's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations, 16th Edition,* (Orange Book) from "**AA**" to "**BP**". The Agency classified this DESI drug product as not having an actual or potential bioequivalence problem on January 7, 1977 (42 FR 1624). There are five companies that have approved Abbreviated New Drug Applications (ANDA's) for this drug product. The reason for this proposed change is that the Agency has evidence from a well-controlled, *in vivo* bioequivalence

study submitted by Roberts Pharmaceutical Corporation (Roberts), the holder of the approved New Drug Application for Pro-Banthine, that Roxane Laboratories' propantheline bromide tablets, 15mg., that meet the *in vitro* determination of bioequivalence, do not meet the Agency's *in vivo* bioequivalence approval criteria.

The Office of Generic Drugs (OGD) thoroughly examined Roberts' study. The Office of Compliance's Division of Scientific Investigations inspected Roberts' manufacturing facilities and Phoenix's (Roberts' contractor) clinical study records. These activities validated the results of the Roberts' study. OGD concluded that Roxane's PB tablets do not fall entirely within the 80-125% confidence interval for C_{max} and AUC when compared to Roberts' Pro-Banthine tablets. This failure to fall entirely within 80-125% confidence intervals does not prove that the products are not bioequivalent. It shows that the criteria for bioequivalence required by OGD were not met. To prove that they are not bioequivalent, the entire confidence interval of either C_{max} or AUC would have to be outside of the 80-125% interval.

Simply stated, the Roberts' study proved neither bioequivalence nor bioinequivalence. This study, however, did raise significant concerns regarding the Agency's original decision to classify PB tablets as "**AA**" (not having actual or potential bioequivalence problems), and not require an *in vivo* bioequivalence study to support the approval of generic versions. Therefore, the Agency is proposing to change the therapeutic equivalence code from a non-bioequivalence problem drug to a bioequivalence problem drug for PB tablets.

You have 60 days in which to submit written comments about this notice to the Director, Division of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research, MPN2, HFD-650, 7500 Standish Place, Rockville, MD 20855. After the Agency reviews the comments, it will print its decision in their next Orange Book supplement following the close of the comment period.

If the proposal is enacted, the Agency will require a firm that holds an approved ANDA for this drug product to submit an *in vivo* bioequivalence study in a supplement [under 21 CFR Section 314.70(b)] to OGD within a specific time period. If an *in vivo* bioequivalence study is not submitted, the Agency will proceed to change the therapeutic code from "**AA**" to "**BP**". If a firm submits a bioequivalence study, the Agency will review the study and then make a determination regarding the therapeutic equivalence code for that product. An applicant with a pending ANDA will have to amend its application with an *in vivo* bioequivalence study, and a firm submitting a new ANDA must include an *in vivo* study in the application.

A firm wishing to submit written comments to the Agency on this notice, may do so within sixty days from the first of the month following the publication of the monthly supplement. A firm may request a copy of the OGD review of Roberts' *in vivo* bioequivalence study by writing to the Agency's Freedom of Information Office (HFI-35), 5600 Fishers Lane, Rockville, MD 20857.

1.4 COURT ORDER REGARDING ABBOTT U.S. PATENT NO. 4112097, (TERAZOSIN HCL)

On April 9, 1996, the United States District Court for the Northern District of Illinois (Eastern Division) issued an order in the case of Abbott Labs v. Geneva Pharmaceuticals, Inc., directing Abbott to remove U.S. Patent No. 4112097 from the Orange Book. To comply with that order, Abbott has requested that FDA remove patent 4112097 from the Orange Book. The FDA complied with this request in the March 1996 cumulative supplement. On April 9, 1996, Abbott appealed the district court's decision to the U.S. Court of Appeals for the Federal Circuit.

1.5 APPLICANT NAME CHANGES

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. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will automatically reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. However, when the applicant name change is one which may not be easily recognized or located in the listing (e.g., White Towne Paulsen [Former Abbreviated Name] is changed to Whiteworth Towne [New Abbreviated Name], the name change will appear in this section and will be identified with an asterisk.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
1ST TEXAS PHARMACEUTICALS INC SUB SCHERER LABORATORIES (1ST TX)	SCHERER LABORATORIES, INC (SCHERER)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
BOEHRINGER MANNHEIM PHARMACEUTICALS CORP (BOEHRINGER MANNHEIM)	BOEHRINGER MANNHEIM CORPORATION THERAPEUTICS DIVISION (BOEHRINGER MANNHEIM)
DAVID BULL LABORATORIES PARTY LTD (BULL D)	FH FAULDING AND CO LTD (FAULDING) **THEN CHANGED TO** FAULDING PHARMACEUTICAL CO (FAULDING)
HOECHST ROUSSEL PHARMACEUTICALS INC (HOECHST ROUSSEL)	HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL)
SCHWARZ PHARMA KREMERS URBAN CO SUB SCHWARZ PHARMA AG (SPKU)	SCHWARZ PHARMA INC (SCHWARZ PHARMA)

1.6 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

The *Approved Drug Products with Therapeutic Equivalence Evaluations* (Prescription Drug Products, OTC Drug Products and the Discontinued Drug Product Lists) is now available on diskette, on a quarterly basis, from the National Technical Information Service. The telephone number for the Subscription Department is (703) 487-6430. Written inquiries regarding this subscription may be forwarded to 5285 Port Royal Road Springfield, VA 22161.

The following *Approved Drug Products with Therapeutic Equivalence Evaluations* files are now available on Internet and are updated each October and April: Prescription Drug Product List; OTC Drug Products; Discontinued Drug Products; and Appendices. The update in October will include drug products that have been approved through August and the update in April will include drug products that have been approved through December.

These files may be accessed on the Internet's World Wide Web. FDA's Internet site replaces the Agency's electronic bulletin board and offers more information, in a more user-friendly form. To access the FDA Home Page, use this Uniform Resource Locator (URL): http://www.fda.gov. You do not need an Internet connection to reach the FDA Home Page; you can use the free dial-up connection (800) 222-0185. For further assistance, please call (301) 443-4908.

The Prescription Drug Products and OTC Drug Product files will be available on a monthly basis in the near future.

1.7 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. 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 approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1995) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

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 as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1995	MAR 1996	JUN 1996	SEP 1996
DRUG PRODUCTS LISTED	9286	9303		
SINGLE SOURCE	2217 (23.9%)	2248 (24.2%)		
MULTISOURCE	7069 (76.1%)	7055 (75.8%)		
THERAPEUTICALLY EQUIVALENT	6437 (69.3%)	6425 (69.0%)		
NOT THERAPEUTICALLY EQUIVALENT	440 (4.7%)	443 (4.8%)		
EXCEPTIONS[1]	192 (2.1%)	187 (2.0%)		
NEW MOLECULAR ENTITIES APPROVED	--	6		
NUMBER OF APPLICANTS	586	592		

[1]Amino acid-containing products of varying composition (see Introduction, page xvi of the List).

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

	ESGIC-PLUS			
+	MIKART	500MG;50MG;40MG	N40085 001	
			MAR 28, 1996	

TABLET; ORAL

	BUTALBITAL, ACETAMINOPHEN AND CAFFEINE			
	MIKART	500MG;50MG;40MG	N89451 001	
			MAY 23, 1988	
+		500MG;50MG;40MG	N89451 001	
			MAY 23, 1988	

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL

	ACETAMINOPHEN AND CODEINE PHOSPHATE			> DLT >	
				> DLT >	
AA	HI TECH PHARMA	120MG/5ML;12MG/5ML	N40119 001	> ADD >	
			APR 26, 1996	> ADD >	
	TYLENOL W/ CODEINE				
AA	JOHNSON RW	120MG/5ML;12MG/5ML	N85057 001	> DLT >	
AA +		120MG/5ML;12MG/5ML	N85057 001	> DLT >	
				> ADD >	
				> ADD >	

TABLET; ORAL

	ACETAMINOPHEN AND CODEINE PHOSPHATE			
AA	GENEVA PHARMS	300MG;30MG	N85291 002	
AA		300MG;60MG	N85964 001	
@		300MG;30MG	N85291 002	
@		300MG;60MG	N85964 001	
AA	HALSEY	300MG;60MG	N86549 001	
@		300MG;60MG	N86549 001	
AA	MIKART	300MG;30MG	N89238 001	
			FEB 25, 1986	
AA		300MG;60MG	N89244 001	
			FEB 25, 1986	
@		300MG;60MG	N89244 001	
			FEB 25, 1986	
	ACETAMINOPHEN AND CODEINE PHOSPHATE #3			
AA	MIKART	300MG;30MG	N89238 001	
			FEB 25, 1986	
AA	SUPERPHARM	300MG;30MG	N89184 001	
			OCT 18, 1985	
@		300MG;30MG	N89184 001	
			OCT 18, 1985	
	ACETAMINOPHEN AND CODEINE PHOSPHATE #4			> DLT >
AA	SUPERPHARM	300MG;60MG	N89185 001	> DLT >
			OCT 18, 1985	

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

	ACETAMINOPHEN AND CODEINE PHOSPHATE #4		
@	SUPERPHARM	300MG;60MG	N89185 001
			OCT 18, 1985
	ACETAMINOPHEN W/ CODEINE PHOSPHATE		
AA	HALSEY	300MG;15MG	N83871 001
AA		300MG;30MG	N83872 001
@		300MG;15MG	N83871 001
@		300MG;30MG	N83872 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

	ANEXSIA		
AA	KING PHARMS	500MG;5MG	N89160 001
			APR 23, 1987
AA	MALLINCKRODT	500MG;5MG	N89160 001
			APR 23, 1987
	ANEXSIA 7.5/650		
AA	KING PHARMS	650MG;7.5MG	N89725 001
			SEP 30, 1987
AA	MALLINCKRODT	650MG;7.5MG	N89725 001
			SEP 30, 1987
	HYDROCODONE BITARTRATE AND ACETAMINOPHEN		
AA	ROYCE LABS	500MG;2.5MG	N40123 003
			MAR 04, 1996
AA		500MG;5MG	N40122 001
			MAR 04, 1996
AA		500MG;7.5MG	N40123 004
			MAR 04, 1996
AA		650MG;7.5MG	N40123 001
			MAR 04, 1996
AA		650MG;10MG	N40123 002
			MAR 04, 1996
AA		750MG;7.5MG	N40122 002
			MAR 04, 1996
AA	VINTAGE PHARMS	500MG;7.5MG	N40144 001
			FEB 22, 1996
AA		650MG;10MG	N40143 001
			FEB 22, 1996
AA		750MG;7.5MG	N40157 001
			APR 12, 1996
	LORTAB		
	UCB	500MG;10MG	N40100 001
			JAN 26, 1996

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
LORTAB
>ADD< + UCB 500MG;10MG N40100 001
>ADD< JAN 26, 1996

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
AB SUPERPHARM 650MG;100MG N71319 001
JAN 06, 1987
@ 650MG;100MG N71319 001
JAN 06, 1987

>ADD< ADAPALENE

>ADD< GEL; TOPICAL
>ADD< DIFFERIN
>ADD< + GALDERMA 0.1% N20380 001
>ADD< MAY 31, 1996

>ADD< SOLUTION; TOPICAL
>ADD< DIFFERIN
>ADD< + GALDERMA 0.1% N20338 001
>ADD< MAY 31, 1996

>ADD< ALLOPURINOL SODIUM

>ADD< INJECTABLE; INJECTION
>ADD< ZYLOPRIM
>ADD< + GLAXO WELLCOME EQ 500MG BASE/VIAL N20298 001
>ADD< MAY 17, 1996

AMINO ACIDS

INJECTABLE; INJECTION
AMINOSYN-HF 8%
ABBOTT 8% N20345 001
APR 04, 1996
HEPATASOL 8%
BAXTER 8% N20360 001
APR 04, 1996

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE
@ PHOENIX LABS NY 100MG N85409 001
@ 200MG N85410 001
@ VINTAGE PHARMS 100MG N85409 001
@ 200MG N85410 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL
BP HALSEY 25MG N85922 001
@ 25MG N85922 001
ENDEP
AB ROCHE 150MG N85303 001
@ 150MG N85303 001

AMOXICILLIN

TABLET, CHEWABLE; ORAL
AMOXICILLIN
>ADD< AB APOTHECON 125MG N64131 001
>ADD< MAY 06, 1996
>ADD< AB 250MG N64131 002
>ADD< MAY 06, 1996
AB CLONMEL HLTH CARE 125MG N64139 001
JAN 29, 1996
AB 250MG N64139 002
JAN 29, 1996

AMOXICILLIN; CLAVULANATE POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
>ADD< AUGMENTIN '200'
>ADD< + SMITHKLINE BEECHAM 200MG/5ML;
>ADD< EQ 28.5MG BASE/5ML N50725 001
>ADD< MAY 31, 1996
>ADD< AUGMENTIN '400'
>ADD< + SMITHKLINE BEECHAM 400MG/5ML;
>ADD< EQ 57MG BASE/5ML N50725 002
>ADD< MAY 31, 1996

TABLET; ORAL
AUGMENTIN '875'
+ SMITHKLINE BEECHAM 875MG;EQ 125MG BASE N50720 001
FEB 13, 1996

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET, CHEWABLE; ORAL

>ADD>		AUGMENTIN '200'			
>ADD>	+	SMITHKLINE BEECHAM	200MG;EQ 28.5MG BASE	N50726 001	
>ADD>				MAY 31, 1996	
>ADD>		AUGMENTIN '400'			
>ADD>	+	SMITHKLINE BEECHAM	400MG;EQ 57MG BASE	N50726 002	
>ADD>				MAY 31, 1996	

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

		ADDERALL 10			
		RICHWOOD PHARM	2.5MG;2.5MG;2.5MG;2.5MG	N11522 007	
				FEB 13, 1996	
		ADDERALL 20			
	+	RICHWOOD PHARM	5MG;5MG;5MG;5MG	N11522 008	
				FEB 13, 1996	

AMPHOTERICIN B

SUSPENSION; ORAL

	FUNGIZONE			
+	BRISTOL MYERS SQUIBB	100MG/ML		N50341 003

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

POWDER FOR RECONSTITUTION; ORAL

		POLYCILLIN-PRB			
AB	+	**APOTHECON**	**EQ 3.5GM BASE/BOT;1GM/BOT**	**N61898 001**	
	@		EQ 3.5GM BASE/BOT;1GM/BOT	N61898 001	
		PROBAMPACIN			
AB		**BIOCRAFT**	**EQ 3.5GM BASE/BOT;1GM/BOT**	**N61741 001**	
	+		EQ 3.5GM BASE/BOT;1GM/BOT	N61741 001	

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

		BUTALBITAL, ASPIRIN & CAFFEINE			
AB		**HALSEY**	**325MG;50MG;40MG**	**N89448 001**	
				DEC 01, 1986	
	@		325MG;50MG;40MG	N89448 001	
				DEC 01, 1986	

ASPIRIN; CARISOPRODOL

TABLET; ORAL

	CARISOPRODOL AND ASPIRIN			
AB	EON LABS	**325MG;200MG**		**N40116 001**
				APR 25, 1996

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET; ORAL

	CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE			
AB	EON LABS	**325MG;200MG;16MG**		**N40118 001**
				APR 16, 1996
	SOMA COMPOUND W/ CODEINE			
AB +	WALLACE PHARMS	**325MG;200MG;16MG**		**N12366 002**
				JUL 11, 1983

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

	LOGEN			
AA	**SUPERPHARM**	**0.025MG;2.5MG**		**N88962 001**
				MAY 10, 1985
	@	0.025MG;2.5MG		N88962 001
				MAY 10, 1985
	LOW-QUEL			
AA	**HALSEY**	**0.025MG;2.5MG**		**N85211 001**
	@	0.025MG;2.5MG		N85211 001

AZATHIOPRINE

TABLET; ORAL

	AZATHIOPRINE			
AB	ROXANE	**50MG**		**N74069 001**
				FEB 16, 1996
	IMURAN			
AB +	GLAXO WELLCOME	**50MG**		**N16324 001**

BACITRACIN

OINTMENT; OPHTHALMIC

		BACITRACIN			
>DLT>	**AT**	**ALTANA**	**500 UNITS/GM**		**N61212 001**
>ADD>	+		500 UNITS/GM		N61212 001
>DLT>	**AT** +	**LILLY**	**500 UNITS/GM**		**N60687 001**

BACITRACIN

OINTMENT; OPHTHALMIC
BACITRACIN
> ADD > @ LILLY 500 UNITS/GM N60687 001

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
BLENOXANE
\+ BRISTOL EQ 15 UNITS BASE/VIAL N50443 001
\+ BRISTOL MYERS SQUIBB EQ 15 UNITS BASE/VIAL N50443 001

BROMPHENIRAMINE MALEATE

TABLET; ORAL
DIMETANE
AA + ROBINS AH 4MG N10799 003
@ WHITEHALL ROBINS 4MG N10799 003

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL
BUSPAR
\+ BRISTOL MYERS SQUIBB 10MG N18731 002
SEP 29, 1986
10MG N18731 002
SEP 29, 1986
\+ 15MG N18731 003
APR 22, 1996
@ 30MG N18731 004
APR 22, 1996

BUTABARBITAL SODIUM

ELIXIR; ORAL
SARISOL
AA HALSEY 30MG/5ML N84723 001
@ 30MG/5ML N84723 001

TABLET; ORAL
SARISOL NO. 1
AA HALSEY 15MG N84719 001
@ 15MG N84719 001
SARISOL NO. 2
AA HALSEY 30MG N84719 002

BUTABARBITAL SODIUM

TABLET; ORAL
SARISOL NO. 2
@ HALSEY 30MG N84719 002

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL
DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT FRESENIUS 25.7MG/100ML;1.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 002
DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
AT FRESENIUS 25.7MG/100ML;2.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 003
DELFLEX W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
AT FRESENIUS 25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 007
JUN 24, 1988
DELFLEX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
AT FRESENIUS 25.7MG/100ML;4.25GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 001
DELFLEX-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT FRESENIUS 25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N18379 004
JUL 07, 1982
DELFLEX-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
AT FRESENIUS 25.7MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N18379 005
JUL 07, 1982
DELFLEX-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
AT FRESENIUS 25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N18379 008
JUN 24, 1988
DELFLEX-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
AT FRESENIUS 25.7MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N18379 006
JUL 07, 1982

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

INPERSOL W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT FRESENIUS 25.7MG/100ML;1.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 002

INPERSOL W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

AT FRESENIUS 25.7MG/100ML;2.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 003

INPERSOL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AT FRESENIUS 25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 007 JUN 24, 1988

INPERSOL W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT FRESENIUS 25.7MG/100ML;4.25GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 001

INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT FRESENIUS 25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N18379 004 JUL 07, 1982

INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

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

AT FRESENIUS 25.7MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N18379 005 JUL 07, 1982

INPERSOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AT FRESENIUS 25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N18379 008 JUN 24, 1988

INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT FRESENIUS 25.7MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N18379 006 JUL 07, 1982

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

AB BIOCRAFT 12.5MG N74433 001 FEB 13, 1996

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

AB	BIOCRAFT	25MG	N74433 002 FEB 13, 1996
AB		50MG	N74433 003 FEB 13, 1996
AB		100MG	N74433 004 FEB 13, 1996
AB	CHELSEA LABS	12.5MG	N74576 001 APR 23, 1996
AB		25MG	N74576 002 APR 23, 1996
AB		50MG	N74576 003 APR 23, 1996
AB		100MG	N74576 004 APR 23, 1996
AB	COPLEY PHARM	12.5MG	N74462 001 FEB 13, 1996
AB		25MG	N74462 002 FEB 13, 1996
AB		50MG	N74462 003 FEB 13, 1996
AB		100MG	N74462 004 FEB 13, 1996
AB	DANBURY PHARMA	12.5MG	N74386 001 MAY 23, 1996
AB		25MG	N74386 002 MAY 23, 1996
AB		50MG	N74386 003 MAY 23, 1996
AB		100MG	N74386 004 MAY 23, 1996
AB	ENDO LABS	12.5MG	N74418 001 FEB 13, 1996
AB		25MG	N74418 002 FEB 13, 1996
AB		50MG	N74418 003 FEB 13, 1996
AB		100MG	N74418 004 FEB 13, 1996
AB	EON LABS	12.5MG	N74519 001 FEB 13, 1996
AB		25MG	N74519 002 FEB 13, 1996
AB		50MG	N74519 003 FEB 13, 1996

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

AB	EON LABS	100MG	N74519 004 FEB 13, 1996
AB	HALLMARK PHARMS	12.5MG	N74477 001 FEB 13, 1996
AB		25MG	N74477 002 FEB 13, 1996
AB		50MG	N74477 003 FEB 13, 1996
AB		100MG	N74477 004 FEB 13, 1996
AB	INVAMED	12.5MG	N74481 001 FEB 13, 1996
AB		25MG	N74481 002 FEB 13, 1996
AB		50MG	N74481 003 FEB 13, 1996
AB		100MG	N74481 004 FEB 13, 1996
AB	LEMMON	12.5MG	N74483 001 FEB 13, 1996
AB		25MG	N74483 002 FEB 13, 1996
AB		50MG	N74483 003 FEB 13, 1996
AB		100MG	N74483 004 FEB 13, 1996
AB	MOVA	12.5MG	N74423 001 FEB 13, 1996
AB		25MG	N74423 002 FEB 13, 1996
AB		50MG	N74423 003 FEB 13, 1996
AB		100MG	N74423 004 FEB 13, 1996
AB	MYLAN	12.5MG	N74434 001 FEB 13, 1996
AB		25MG	N74434 002 FEB 13, 1996
AB		50MG	N74434 003 FEB 13, 1996
AB		100MG	N74434 004 FEB 13, 1996
AB	NOVOPHARM	12.5MG	N74322 001 FEB 13, 1996

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

AB	NOVOPHARM	25MG	N74322 002 FEB 13, 1996
AB		50MG	N74322 003 FEB 13, 1996
AB		100MG	N74322 004 FEB 13, 1996
AB	PAR PHARM	12.5MG	N74493 001 FEB 13, 1996
AB		25MG	N74493 002 FEB 13, 1996
AB		50MG	N74493 003 FEB 13, 1996
AB		100MG	N74493 004 FEB 13, 1996
AB	ROYCE LABS	12.5MG	N74451 001 FEB 13, 1996
AB		25MG	N74451 002 FEB 13, 1996
AB		50MG	N74451 003 FEB 13, 1996
AB		100MG	N74451 004 FEB 13, 1996
AB	WESTWARD PHARM	12.5MG	N74505 001 FEB 13, 1996
AB		25MG	N74505 002 FEB 13, 1996
AB		50MG	N74505 003 FEB 13, 1996
AB		100MG	N74505 004 FEB 13, 1996

CARBAMAZEPINE

TABLET, EXTENDED RELEASE; ORAL
TEGRETOL-XR

+	CIBA GEIGY	100MG	N20234 001 MAR 25, 1996
+		200MG	N20234 002 MAR 25, 1996
+		400MG	N20234 003 MAR 25, 1996

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

AA	WEST WARD PHARM	350MG	N40124 001	JAN 24, 1996

CEFACLOR

CAPSULE; ORAL
CEFACLOR

> ADD > AB	MARSAM	EQ 250MG BASE	N64148 001	MAY 23, 1996
> ADD > AB		EQ 500MG BASE	N64148 002	MAY 23, 1996

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
ANCEF IN DEXTROSE 5% IN PLASTIC CONTAINER

+	BAXTER	EQ 10MG BASE/ML	N50566 003	JUN 08, 1983
+		EQ 20MG BASE/ML	N50566 004	JUN 08, 1983
@		EQ 10MG BASE/ML	N50566 003	JUN 08, 1983
@		EQ 20MG BASE/ML	N50566 004	JUN 08, 1983

CEFEPIME HYDROCHLORIDE (ARGININE FORMULATION)

INJECTABLE; INJECTION
MAXIPIME

+	BRISTOL MYERS SQUIBB	EQ 500MG BASE/VIAL	N50679 001	JAN 18, 1996
+		EQ 1GM BASE/VIAL	N50679 002	JAN 18, 1996
+		EQ 2GM BASE/VIAL	N50679 003	JAN 18, 1996

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

AB	YOSHITOMI	EQ 250MG BASE	N62872 001	JUN 20, 1988

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

AB	YOSHITOMI	EQ 500MG BASE	N62871 001	JUL 05, 1988
@		EQ 250MG BASE	N62872 001	JUN 20, 1988
@		EQ 500MG BASE	N62871 001	JUL 05, 1988

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
CEPHALOTHIN SODIUM W/ DEXTROSE IN PLASTIC CONTAINER

> DLT > +	BAXTER	EQ 20MG BASE/ML	N62422 003	JAN 31, 1984
> DLT >		EQ 20MG BASE/ML	N62422 005	JUL 16, 1991
> DLT >		EQ 20MG BASE/ML	N62730 001	MAR 05, 1987
> DLT > +		EQ 40MG BASE/ML	N62422 004	JAN 31, 1984
> DLT >		EQ 40MG BASE/ML	N62422 006	JUL 16, 1991
> DLT >		EQ 40MG BASE/ML	N62730 002	MAR 05, 1987
> ADD > @		EQ 20MG BASE/ML	N62422 003	JAN 31, 1984
> ADD > @		EQ 20MG BASE/ML	N62422 005	JUL 16, 1991
> ADD > @		EQ 20MG BASE/ML	N62730 001	MAR 05, 1987
> ADD > @		EQ 40MG BASE/ML	N62422 004	JAN 31, 1984
> ADD > @		EQ 40MG BASE/ML	N62422 006	JUL 16, 1991
> ADD > @		EQ 40MG BASE/ML	N62730 002	MAR 05, 1987

CEPHALOTHIN SODIUM W/ SODIUM CHLORIDE IN PLASTIC CONTAINER

> DLT > +	BAXTER	EQ 20MG BASE/ML	N62422 001	JAN 31, 1984
> DLT > +		EQ 40MG BASE/ML	N62422 002	JAN 31, 1984
> ADD > @		EQ 20MG BASE/ML	N62422 001	JAN 31, 1984
> ADD > @		EQ 40MG BASE/ML	N62422 002	JAN 31, 1984

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

AB	HALSEY	5MG	N85340 001	
AB		10MG	N85339 001	
AB		25MG	N84685 001	
@		5MG	N85340 001	
@		10MG	N85339 001	
@		25MG	N84685 001	

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
CHLORHEXIDINE GLUCONATE

> ADD >	AT	HI TECH PHARMA	0.12%	N74356 001	
> ADD >				MAY 07, 1996	

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

AB	BARR	100MG	N88812 001	OCT 19, 1984
AB		100MG	N89446 001	NOV 17, 1986
AB		250MG	N88813 001	OCT 19, 1984
AB		250MG	N89447 001	NOV 17, 1986
@		100MG	N88812 001	OCT 19, 1984
@		100MG	N89446 001	NOV 17, 1986
@		250MG	N88813 001	OCT 19, 1984
@		250MG	N89447 001	NOV 17, 1986
AB	HALSEY	100MG	N89321 001	JAN 16, 1986
AB		250MG	N88662 001	JAN 09, 1986
@		100MG	N89321 001	JAN 16, 1986
@		250MG	N88662 001	JAN 09, 1986

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

AB	SUPERPHARM	250MG	N88695 001	SEP 17, 1984
@		250MG	N88695 001	SEP 17, 1984

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

AB	SUPERPHARM	50MG	N87247 001	FEB 09, 1983
@		50MG	N87247 001	FEB 09, 1983

CHOLESTYRAMINE

POWDER; ORAL
PREVALITE

AB	UPSHER SMITH	EQ 4GM RESIN/PACKET	N73263 001	FEB 22, 1996

QUESTRAN

AB	+ BRISTOL MYERS	EQ 4GM RESIN/PACKET	N16640 001	
AB		EQ 4GM RESIN/SCOOPFUL	N16640 003	

QUESTRAN LIGHT

AB	+ BRISTOL MYERS	EQ 4GM RESIN/PACKET	N19669 001	DEC 05, 1988
AB		EQ 4GM RESIN/PACKET	N19669 001	DEC 05, 1988
AB		EQ 4GM RESIN/SCOOPFUL	N19669 003	DEC 05, 1988

CHROMIC CHLORIDE

INJECTABLE; INJECTION
CHROMIC CHLORIDE

AP	FUJISAWA	EQ 0.004MG CHROMIUM/ML	N19271 001	MAY 05, 1987
@		EQ 0.004MG CHROMIUM/ML	N19271 001	MAY 05, 1987

CHROMIC CHLORIDE IN PLASTIC CONTAINER

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

CHROMIC CHLORIDE

INJECTABLE; INJECTION
CHROMIC CHLORIDE IN PLASTIC CONTAINER

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

CIMETIDINE

TABLET; ORAL
CIMETIDINE

AB	DANBURY PHARMA	800MG	**N74316 001**	FEB 28, 1996
AB	INVAMED	200MG	**N74506 001**	JAN 24, 1996
AB		300MG	**N74506 002**	JAN 24, 1996
AB		400MG	**N74506 003**	JAN 24, 1996
AB		800MG	**N74506 004**	JAN 24, 1996

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

AP	MOVA	**EQ 300MG BASE/2ML**	**N74428 001**	APR 25, 1996

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL
CIPRO

	BAYER	EQ 100MG BASE	N19537 001	APR 08, 1996

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL
CLOBETASOL PROPIONATE

AB	FOUGERA	0.05%	**N74407 001**	FEB 23, 1996

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL
ANAFRANIL

AB	CIBA GEIGY	25MG	**N19906 001**	DEC 29, 1989
AB	+	50MG	**N19906 002**	DEC 29, 1989
AB		75MG	**N19906 003**	DEC 29, 1989

CLOMIPRAMINE HCL

AB	GENEVA PHARMS	25MG	**N74364 001**	MAR 29, 1996
AB		50MG	**N74364 002**	MAR 29, 1996
AB		75MG	**N74364 003**	MAR 29, 1996

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PHERAZINE VC W/ CODEINE

AA	HALSEY	10MG/5ML;5MG/5ML; 6.25MG/5ML	**N88870 001**	MAR 02, 1987
	@	10MG/5ML;5MG/5ML; 6.25MG/5ML	N88870 001	MAR 02, 1987

> ADD >

CORTICORELIN OVINE TRIFLUTATE

INJECTABLE; INJECTION
ACTHREL

+	FERRING LABS	EQ 0.1MG BASE/VIAL	N20162 001	MAY 23, 1996

CROMOLYN SODIUM

CONCENTRATE; ORAL
GASTROCROM

+	FISONS	100MG/5ML	N20479 001	FEB 29, 1996

CYANOCOBALAMIN

INJECTABLE; INJECTION
BETALIN 12

>_DLT_>	**AP**	LILLY	**1MG/ML**	**N80855 002**
>_ADD_>		@	1MG/ML	N80855 002

CYCLOTHIAZIDE

TABLET; ORAL
ANHYDRON

>_DLT_>		+ LILLY	2MG	N13157 002
>_ADD_>		@	2MG	N13157 002

CYPROHEPTADINE HYDROCHLORIDE

SYRUP; ORAL
CYPROHEPTADINE HCL

>_DLT_>	**AA**	HALSEY	**2MG/5ML**	**N89199 001**
>_DLT_>				**JUL 03, 1986**
>_ADD_>		@	2MG/5ML	N89199 001
>_ADD_>				JUL 03, 1986

DALTEPARIN SODIUM

INJECTABLE; INJECTION
FRAGMIN

	+	PHARMACIA	5,000 IU/0.2ML	N20287 003
				MAR 18, 1996

DAUNORUBICIN CITRATE

INJECTABLE, LIPOSOMAL; INJECTION
DAUNOXOME

	+	NEXSTAR	EQ 2MG BASE/ML	N50704 002
				APR 08, 1996

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

AB		EON LABS	**10MG**	**N74430 001**
				FEB 09, 1996

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

AB		EON LABS	**150MG**	**N74430 002**
				FEB 09, 1996

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
DEXACIDIN

AT		CIBA	**0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM**	**N62566 001**
				FEB 22, 1985
AT		IOLAB	**0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM**	**N62566 001**
				FEB 22, 1985

SUSPENSION/DROPS; OPHTHALMIC
DEXACIDIN

AT		CIBA	**0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML**	**N62544 001**
				OCT 29, 1984
AT		IOLAB	**0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML**	**N62544 001**
				OCT 29, 1984

DEXFENFLURAMINE HYDROCHLORIDE

CAPSULE; ORAL
REDUX

	+	INTERNEURON	15MG	N20344 001
				APR 29, 1996

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL
DEXTROAMPHETAMINE SULFATE

AA		HALSEY	**10MG**	**N83930 001**
	@		10MG	N83930 001
AA		MM MAST	**5MG**	**N86521 001**
	@		5MG	N86521 001
AA	+	REXAR	**10MG**	**N84051 002**
	+		10MG	N84051 002

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

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

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

	DICLOFENAC SODIUM			
AB	PUREPAC PHARM	**50MG**	**N74514 001**	
			MAR 26, 1996	
AB		**75MG**	**N74514 002**	
			MAR 26, 1996	

TABLET, EXTENDED RELEASE; ORAL

	VOLTAREN-XR			
	+ GEIGY	100MG	N20254 001	
			MAR 08, 1996	

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

	DICYCLOMINE HCL			
AB	LANNETT	**10MG**	**N84285 001**	

DIFLUNISAL

TABLET; ORAL

	DIFLUNISAL			
>ADD> **AB**	PUREPAC PHARM	**250MG**	**N74285 001**	
>ADD>			MAY 07, 1996	
>ADD> **AB**		**500MG**	**N74285 002**	
>ADD>			MAY 07, 1996	

DIGOXIN

INJECTABLE; INJECTION

	DIGOXIN			
>ADD> **AP**	SANOFI WINTHROP	**0.25MG/ML**	**N40093 001**	
>ADD>			MAY 16, 1996	

DIGOXIN

INJECTABLE; INJECTION

	DIGOXIN PEDIATRIC			
AP	SANOFI WINTHROP	**0.1MG/ML**	**N40092 001**	
			APR 25, 1996	
	LANOXIN			
	+ GLAXO WELLCOME	0.1MG/ML	N09330 004	
	LANOXIN PEDIATRIC			
AP	+ GLAXO WELLCOME	**0.1MG/ML**	**N09330 004**	

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

	CARDIZEM			
AP	+ HOECHST MARION RSSL	**5MG/ML**	**N20027 001**	
			OCT 24, 1991	
	DILTIAZEM HCL			
AP	BEDFORD	**5MG/ML**	**N74617 001**	
			FEB 28, 1996	

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

	DIPHENHYDRAMINE HCL			
AA	HALSEY	**50MG**	**N87914 001**	
			JUN 04, 1984	
	@	50MG	N87914 001	
			JUN 04, 1984	

ELIXIR; ORAL

	BELIX			
AA	HALSEY	**12.5MG/5ML**	**N86586 001**	
			OCT 03, 1983	
	@	12.5MG/5ML	N86586 001	
			OCT 03, 1983	

DISOPYRAMIDE PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL

	DISOPYRAMIDE PHOSPHATE			
B*	KV PHARM	**EQ 100MG BASE**	**N71929 001**	
			AUG 19, 1988	
	@	EQ 100MG BASE	N71929 001	
			AUG 19, 1988	

DISOPYRAMIDE PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL

	NORPACE CR			
AB	SEARLE	EQ 100MG BASE	N18655 001	
			JUL 20, 1982	
		EQ 100MG BASE	N18655 001	
			JUL 20, 1982	

> ADD > DOCETAXEL

> ADD > INJECTABLE; INJECTION

> ADD >	TAXOTERE			
> ADD >	+ RHONE POULENC	EQ 40MG BASE/ML	N20449 001	
> ADD >			MAY 14, 1996	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

	DOPAMINE HCL			
> ADD > AP	SANOFI WINTHROP	40MG/ML	N74403 001	
> ADD >			MAY 23, 1996	

DOXYCYCLINE HYCLATE

TABLET; ORAL

	DOXYCYCLINE HYCLATE			
AB	SUPERPHARM	EQ 100MG BASE	N62494 001	
			FEB 20, 1985	
	@	EQ 100MG BASE	N62494 001	
			FEB 20, 1985	

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

	EDROPHONIUM CHLORIDE			
AP	STERIS	10MG/ML	N40044 001	
			MAR 20, 1996	
	EDROPHONIUM CHLORIDE PRESERVATIVE FREE			
AP	STERIS	10MG/ML	N40043 001	
			MAR 20, 1996	
	TENSILON PRESERVATIVE FREE			
AP +	ROCHE	10MG/ML	N07959 002	

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

	LIDOCAINE HCL W/ EPINEPHRINE			
AP	ABBOTT	0.01MG/ML;1%	N83154 001	
	@	0.01MG/ML;1%	N83154 001	

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

	ERYTHROCIN			
AP	ABBOTT	EQ 500MG BASE/VIAL	N62586 001	
			JAN 04, 1988	
AP		EQ 1GM BASE/VIAL	N62586 002	
			JAN 04, 1988	
	@	EQ 500MG BASE/VIAL	N62586 001	
			JAN 04, 1988	
	@	EQ 1GM BASE/VIAL	N62586 002	
			JAN 04, 1988	

ESTRADIOL

INSERT, EXTENDED RELEASE; VAGINAL

	ESTRING			
	+ PHARMACIA	0.0075MG/24HR	N20472 001	
			APR 26, 1996	

TABLET; ORAL

	ESTRACE			
AB	BRISTOL MYERS SQUIBB	0.5MG	N81295 001	
			JUN 30, 1993	
AB		1MG	N84499 001	
AB	+	2MG	N84500 001	
	ESTRADIOL			
AB	WATSON LABS	0.5MG	N40114 003	
			MAR 14, 1996	
AB		1MG	N40114 001	
			MAR 14, 1996	
AB		2MG	N40114 002	
			MAR 14, 1996	

ESTRONE

INJECTABLE; INJECTION

	ESTROGENIC SUBSTANCE		
BP +	WYETH AYERST	2MG/ML	N83488 001

ESTRONE

INJECTABLE; INJECTION
ESTROGENIC SUBSTANCE
@ WYETH AYERST 2MG/ML N83488 001
NATURAL ESTROGENIC SUBSTANCE-ESTRONE
BP STERIS 2MG/ML N85237 001 NOV 23, 1982
\+ 2MG/ML N85237 001 NOV 23, 1982

ETOPOSIDE

INJECTABLE; INJECTION
ETOPOSIDE
AP LEDERLE LABS 20MG/ML N74513 001 MAR 14, 1996
AP PHARMACHEMIE (NL) 20MG/ML N74227 001 FEB 22, 1996

> ADD > ETOPOSIDE PHOSPHATE

> ADD > INJECTABLE; INJECTION
> ADD > ETOPOPHOS
> ADD > \+ BRISTOL MYERS SQUIBB EQ 100MG BASE/VIAL N20457 001
> ADD > MAY 17, 1996

EVANS BLUE

INJECTABLE; INJECTION
EVANS BLUE
@ PARKE DAVIS 0.5% N08041 001

FAMCICLOVIR

TABLET; ORAL
FAMVIR
SMITHKLINE BEECHAM 250MG N20363 001 APR 26, 1996

FAMOTIDINE

INJECTABLE; INJECTION
> ADD > PEPCID IV PRESERVATIVE FREE
> ADD > \+ MERCK 10MG/ML N19510 004 NOV 04, 1986
> ADD >

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL
AP \+ PHARMACIA 50MG/ML N40023 001 OCT 18, 1991
AP 50MG/ML N40023 001 OCT 18, 1991

FLUOROURACIL
AP ROCHE 50MG/ML N12209 001
AP \+ 50MG/ML N12209 001

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL
AB SUPERPHARM 15MG N71659 001 AUG 04, 1988
AB 30MG N71660 001 AUG 04, 1988
@ 15MG N71659 001 AUG 04, 1988
@ 30MG N71660 001 AUG 04, 1988
> DLT > AB WARNER CHILCOTT 30MG N71768 001 DEC 04, 1987
> DLT >
> ADD > @ 30MG N71768 001 DEC 04, 1987
> ADD >

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION
FLOVENT
GLAXO WELLCOME 0.044MG/INH N20548 001 MAR 27, 1996
0.11MG/INH N20548 002 MAR 27, 1996
\+ 0.22MG/INH N20548 003 MAR 27, 1996

FOLIC ACID

TABLET; ORAL
FOLIC ACID

AA	HALSEY	1MG	N83598 001	
@		1MG	N83598 001	

FUROSEMIDE

TABLET; ORAL
FUROSEMIDE

AB	SUPERPHARM	20MG	N18370 002 JUN 26, 1984
AB		40MG	N18370 001 FEB 10, 1983
@		20MG	N18370 002 JUN 26, 1984
@		40MG	N18370 001 FEB 10, 1983
AB	ZENITH GOLDLINE	20MG	N18413 001 NOV 30, 1983
AB		40MG	N18413 002 NOV 30, 1983
AB	ZENITH LABS	20MG	N18413 001 NOV 30, 1983
AB		40MG	N18413 002 NOV 30, 1983

GANCICLOVIR

IMPLANT; IMPLANTATION
VITRASERT

+	CHIRON VISION	4.5-6.4MG	N20569 001 MAR 04, 1996

GANCICLOVIR SODIUM

INJECTABLE; INJECTION

> DLT >	CYTOVENE			
> DLT >	+ SYNTEX	EQ 500MG BASE/VIAL	N19661 001 JUN 23, 1989	
> DLT >				
> ADD >	CYTOVENE IV			
> ADD >	+ SYNTEX	EQ 500MG BASE/VIAL	N19661 001 JUN 23, 1989	
> ADD >				

GEMCITABINE HYDROCHLORIDE

INJECTABLE; INJECTION
GEMZAR

+	LILLY	EQ 200MG BASE/VIAL	N20509 001 MAY 15, 1996
+		EQ 1GM BASE/VIAL	N20509 002 MAY 15, 1996

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GENTAMICIN SULFATE

AP	ABBOTT	EQ 60MG BASE/100ML	N62413 006 AUG 11, 1983
AP		EQ 70MG BASE/100ML	N62413 007 AUG 11, 1983
AP		EQ 80MG BASE/100ML	N62413 008 AUG 11, 1983
AP		EQ 90MG BASE/100ML	N62413 009 AUG 11, 1983
AP		EQ 100MG BASE/100ML	N62413 010 AUG 11, 1983
AP		EQ 1.2MG BASE/ML	N62413 001 AUG 11, 1983
AP		EQ 1.4MG BASE/ML	N62413 002 AUG 11, 1983
AP		EQ 1.6MG BASE/ML	N62413 003 AUG 11, 1983
AP		EQ 1.8MG BASE/ML	N62413 004 AUG 11, 1983
AP		EQ 2MG BASE/ML	N62413 005 AUG 11, 1983
@		EQ 60MG BASE/100ML	N62413 006 AUG 11, 1983
@		EQ 70MG BASE/100ML	N62413 007 AUG 11, 1983
@		EQ 80MG BASE/100ML	N62413 008 AUG 11, 1983
@		EQ 90MG BASE/100ML	N62413 009 AUG 11, 1983
@		EQ 100MG BASE/100ML	N62413 010 AUG 11, 1983
@		EQ 1.2MG BASE/ML	N62413 001 AUG 11, 1983
@		EQ 1.4MG BASE/ML	N62413 002 AUG 11, 1983

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GENTAMICIN SULFATE

	@ ABBOTT	EQ 1.6MG BASE/ML	N62413 003	AUG 11, 1983
	@	EQ 1.8MG BASE/ML	N62413 004	AUG 11, 1983
	@	EQ 2MG BASE/ML	N62413 005	AUG 11, 1983

OINTMENT; OPHTHALMIC
GENTACIDIN

AT	CIBA	EQ 0.3% BASE	N62501 001	JUL 26, 1984
AT	IOLAB	EQ 0.3% BASE	N62501 001	JUL 26, 1984

SOLUTION/DROPS; OPHTHALMIC
GENTACIDIN

AT	CIBA	EQ 0.3% BASE	N62480 001	MAR 30, 1984
AT	IOLAB	EQ 0.3% BASE	N62480 001	MAR 30, 1984

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE

AB	NOVOPHARM	5MG	N74387 001	MAR 04, 1996
AB		10MG	N74387 002	MAR 04, 1996

GLUTETHIMIDE

TABLET; ORAL
GLUTETHIMIDE

> DLT >	HALSEY	250MG	N89458 001	OCT 10, 1986
> DLT >				
> ADD >	@	250MG	N89458 001	OCT 10, 1986
> ADD >				

GLYBURIDE

TABLET; ORAL
GLYNASE

AB	UPJOHN	3MG	N20051 002	MAR 04, 1992
AB +		3MG	N20051 002	MAR 04, 1992
+		6MG	N20051 004	SEP 24, 1993
@		6MG	N20051 004	SEP 24, 1993

GOSERELIN ACETATE

IMPLANT; IMPLANTATION
ZOLADEX

+	ZENECA	EQ 10.8MG BASE	N20578 001	JAN 11, 1996

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

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

AT	BAUSCH AND LOMB	0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML	N64047 001	JAN 31, 1996

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALDOL DECANOATE 100

+	JOHNSON RW	EQ 100MG BASE/ML	N18701 002	OCT 31, 1989

HALOPROGIN

CREAM; TOPICAL
HALOTEX

+	WESTWOOD SQUIBB	1%	N16942 001	
@		1%	N16942 001	

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

AA	HALSEY	10MG	N89218 001 JAN 22, 1986
@		10MG	N89218 001 JAN 22, 1986

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDRO-D

AB	HALSEY	25MG	N86504 001
AB		50MG	N83891 002
@		25MG	N86504 001
@		50MG	N83891 002

HYDROCHLOROTHIAZIDE

AB	BARR	50MG	N84771 001
@		50MG	N84771 001
AB	SUPERPHARM	25MG	N88827 001 DEC 28, 1984
AB		50MG	N88828 001 DEC 28, 1984
AB		100MG	N88829 001 DEC 28, 1984
@		25MG	N88827 001 DEC 28, 1984
@		50MG	N88828 001 DEC 28, 1984
@		100MG	N88829 001 DEC 28, 1984

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	NOVOPHARM	15MG;250MG	N71819 001 APR 08, 1988
AB		25MG;250MG	N71820 001 APR 08, 1988
AB		30MG;500MG	N71821 001 APR 08, 1988
AB		50MG;500MG	N71822 001 APR 08, 1988
@		15MG;250MG	N71819 001 APR 08, 1988

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

@	NOVOPHARM	25MG;250MG	N71820 001 APR 08, 1988
@		30MG;500MG	N71821 001 APR 08, 1988
@		50MG;500MG	N71822 001 APR 08, 1988
AB	PARKE DAVIS	15MG;250MG	N71897 001 NOV 23, 1987
AB		25MG;250MG	N71898 001 NOV 23, 1987
AB		30MG;500MG	N71899 001 NOV 23, 1987
AB		50MG;500MG	N71900 001 NOV 23, 1987
@		15MG;250MG	N71897 001 NOV 23, 1987
@		25MG;250MG	N71898 001 NOV 23, 1987
@		30MG;500MG	N71899 001 NOV 23, 1987
@		50MG;500MG	N71900 001 NOV 23, 1987

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	SIDMAK LABS NJ	25MG;37.5MG	N74026 001 APR 26, 1996
AB		50MG;75MG	N73467 001 JAN 31, 1996

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

AT	AMBIX	1%	N86080 001
AT		2.5%	N86271 001
@		1%	N86080 001
@		2.5%	N86271 001

OINTMENT; TOPICAL
HYDROCORTISONE

AT	AMBIX	1%	N86079 001

HYDROCORTISONE

OINTMENT; TOPICAL

HYDROCORTISONE			
AT AMBIX	**2.5%**	**N86272 001**	
@	1%	N86079 001	
@	2.5%	N86272 001	
PENECORT			
AT ALLERGAN HERBERT	**2.5%**	**N88217 001 JUN 06, 1984**	
@	2.5%	N88217 001 JUN 06, 1984	

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-HYDROCORT			
AP ABBOTT	**EQ 100MG BASE/VIAL**	**N85928 001**	
@	EQ 100MG BASE/VIAL	N85928 001	

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATE			
AB INVAMED	**200MG**	**N40150 001 JAN 27, 1996**	

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HCL			
AB HALSEY	**10MG**	**N89366 001 MAY 02, 1988**	
@	10MG	N89366 001 MAY 02, 1988	
AB SUPERPHARM	**10MG**	**N88794 001 DEC 05, 1984**	
AB	**25MG**	**N88795 001 DEC 05, 1984**	
AB	**50MG**	**N88796 001 DEC 05, 1984**	> ADD >
@	10MG	N88794 001 DEC 05, 1984	> ADD >
@	25MG	N88795 001 DEC 05, 1984	> ADD >

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HCL			
@ SUPERPHARM	50MG	N88796 001 DEC 05, 1984	

IBUPROFEN

SUSPENSION; ORAL

CHILDREN'S MOTRIN			> DLT >
BX + MCNEIL CONS PRODS	**100MG/5ML**	**N19842 001 SEP 19, 1989**	> DLT >
			> DLT >
MOTRIN			> ADD >
BX + MCNEIL CONS PRODS	100MG/5ML	N19842 001 SEP 19, 1989	> ADD >
			> ADD >

TABLET; ORAL

IBUPROFEN		
AB HALSEY	**300MG**	**N71028 001 MAR 23, 1987**
AB	**400MG**	**N71029 001 MAR 23, 1987**
AB	**600MG**	**N71030 001 MAR 23, 1987**
AB	**800MG**	**N72137 001 FEB 05, 1988**
@	300MG	N71028 001 MAR 23, 1987
@	400MG	N71029 001 MAR 23, 1987
@	600MG	N71030 001 MAR 23, 1987
@	800MG	N72137 001 FEB 05, 1988

INDAPAMIDE

TABLET; ORAL

INDAPAMIDE			
AB INVAMED	**1.25MG**	**N74594 001 MAY 23, 1996**	
AB	**2.5MG**	**N74594 002 MAY 23, 1996**	
AB MYLAN	**2.5MG**	**N74461 001 MAR 27, 1996**	

INDAPAMIDE

TABLET; ORAL

INDAPAMIDE

AB	ZENITH GOLDLINE	1.25MG		N74299 002 APR 29, 1996
AB		2.5MG		N74299 001 JUL 27, 1995
AB	ZENITH LABS	2.5MG		N74299 001 JUL 27, 1995

LOZOL

AB	RHONE POULENC RORER	1.25MG		N18538 002 APR 29, 1993

INDINAVIR SULFATE

CAPSULE; ORAL

CRIXIVAN

	MERCK	EQ 200MG BASE		N20685 003 MAR 13, 1996
+		EQ 400MG BASE		N20685 001 MAR 13, 1996

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

AB	HALSEY	25MG		N70782 001 JUN 03, 1987
AB		50MG		N70635 001 JUN 03, 1987
@		25MG		N70782 001 JUN 03, 1987
@		50MG		N70635 001 JUN 03, 1987
> DLT > AB	PARKE DAVIS	25MG		N18806 001 NOV 23, 1984
> DLT > AB		50MG		N18806 002 NOV 23, 1984
> ADD > @		25MG		N18806 001 NOV 23, 1984
> ADD > @		50MG		N18806 002 NOV 23, 1984

IODIXANOL

INJECTABLE; INJECTION

VISIPAQUE 270

+	NYCOMED	55%	N20351 001 MAR 22, 1996

VISIPAQUE 320

+	NYCOMED	65.2%	N20351 002 MAR 22, 1996

IOPAMIDOL

INJECTABLE; INJECTION

ISOVUE-200

@	BRACCO	41%	N20327 001 OCT 12, 1994

ISOVUE-250

	BRACCO	51%	N20327 002 OCT 12, 1994

ISOVUE-300

	BRACCO	61%	N20327 003 OCT 12, 1994

ISOVUE-370

	BRACCO	76%	N20327 004 OCT 12, 1994

INJECTABLE; INTRAVASCULAR

ISOVUE-200

@	BRACCO	41%	N20327 001 OCT 12, 1994

ISOVUE-250

	BRACCO	51%	N20327 002 OCT 12, 1994

ISOVUE-300

	BRACCO	61%	N20327 003 OCT 12, 1994

ISOVUE-370

	BRACCO	76%	N20327 004 OCT 12, 1994

IRON DEXTRAN

INJECTABLE; INJECTION

DEXFERRUM

BP	LUITPOLD	EQ 50MG IRON/ML	N40024 001 FEB 23, 1996

ISOSORBIDE MONONITRATE

TABLET; ORAL
MONOKET

> DLT >	+	SCHWARZ	10MG	N20215 002
> DLT >				JUN 30, 1993
> ADD >			10MG	N20215 002
> ADD >				JUN 30, 1993

TABLET, EXTENDED RELEASE; ORAL
IMDUR

	@	SCHERING	30MG	N20225 001
				AUG 12, 1993
	+		30MG	N20225 001
				AUG 12, 1993

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
KETALAR

AP	+	PARKE DAVIS	EQ 50MG BASE/ML	N16812 002
AP	+		EQ 100MG BASE/ML	N16812 003

KETAMINE HCL

AP		BEDFORD	EQ 50MG BASE/ML	N74524 001
				MAR 22, 1996
AP			EQ 100MG BASE/ML	N74524 002
				MAR 22, 1996

LIDOCAINE

FILM, EXTENDED RELEASE; BUCCAL
LIDOCAINE

> ADD >	+	NOVEN	23MG/PATCH	N20575 001
> ADD >				MAY 21, 1996
> ADD >	+		46.1MG/PATCH	N20575 002
> ADD >				MAY 21, 1996

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL

AP		ABBOTT	20%	N89362 001
				MAY 25, 1988
	@		20%	N89362 001
				MAY 25, 1988

LIDOCAINE HYDROCHLORIDE

SOLUTION; ORAL
LIDOCAINE HCL

AT		MORTON GROVE	2%	N87872 001
				NOV 18, 1982

LIDOCAINE HCL VISCOUS

AT		INTL MEDICATION	2%	N86389 001
				FEB 02, 1982
	@		2%	N86389 001
				FEB 02, 1982

MYLOCAINE

AT		MORTON GROVE	2%	N87872 001
				NOV 18, 1982

SOLUTION; TOPICAL
ANESTACON

AT	+	ALCON	2%	N80429 001
AT	+	POLYMEDICA	2%	N80429 001

LIDOCAINE HCL

AT		MORTON GROVE	4%	N87881 001
				NOV 18, 1982

MYLOCAINE

AT		MORTON GROVE	4%	N87881 001
				NOV 18, 1982

LINDANE

CREAM; TOPICAL
KWELL

	+	REED AND CARNRICK	1%	N06309 001
			1%	N84218 001
	@		1%	N06309 001
	+		1%	N84218 001

LOTION; TOPICAL
KWELL

AT	+	REED AND CARNRICK	1%	N06309 003
AT			1%	N84218 002
AT	+		1%	N84218 002
	@		1%	N06309 003

SHAMPOO; TOPICAL
KWELL

AT	+	REED AND CARNRICK	1%	N10718 001
AT			1%	N84219 001
AT	+		1%	N84219 001
	@		1%	N10718 001

LITHIUM CITRATE

SYRUP; ORAL

	CIBALITH-S		
AA	SOLVAY	EQ 300MG CARBONATE/5ML	N17672 001
	LITHONATE		
	@ SOLVAY	EQ 300MG CARBONATE/5ML	N17672 001

LORACARBEF

CAPSULE; ORAL

	LORABID		
	+ LILLY	200MG	N50668 001 DEC 31, 1991
		200MG	N50668 001 DEC 31, 1991
	+	400MG	N50668 002 APR 05, 1996

LORAZEPAM

TABLET; ORAL

	LORAZEPAM		
AB	HALSEY	0.5MG	N71434 001 SEP 01, 1987
AB		1MG	N71435 001 SEP 01, 1987
AB		2MG	N71436 001 SEP 01, 1987
	@	0.5MG	N71434 001 SEP 01, 1987
	@	1MG	N71435 001 SEP 01, 1987
	@	2MG	N71436 001 SEP 01, 1987
AB	SUPERPHARM	0.5MG	N71245 001 FEB 09, 1987
AB		1MG	N71246 001 FEB 09, 1987
AB		2MG	N71247 001 FEB 09, 1987
	@	0.5MG	N71245 001 FEB 09, 1987
	@	1MG	N71246 001 FEB 09, 1987
	@	2MG	N71247 001 FEB 09, 1987

MANGANESE CHLORIDE

INJECTABLE; INJECTION

	MANGANESE CHLORIDE IN PLASTIC CONTAINER		
	ABBOTT	EQ 0.1MG MANGANESE/ML	N18962 001 JUN 26, 1986
	@	EQ 0.1MG MANGANESE/ML	N18962 001 JUN 26, 1986

MANGANESE SULFATE

INJECTABLE; INJECTION

	MANGANESE SULFATE		
	FUJISAWA	EQ 0.1MG MANGANESE/ML	N19228 001 MAY 05, 1987
	@	EQ 0.1MG MANGANESE/ML	N19228 001 MAY 05, 1987

MECLOFENAMATE SODIUM

CAPSULE; ORAL

	MECLOFENAMATE SODIUM		
AB	BARR	EQ 50MG BASE	N72848 001 MAR 20, 1989
AB		EQ 100MG BASE	N72809 001 MAR 20, 1989
	@	EQ 50MG BASE	N72848 001 MAR 20, 1989
	@	EQ 100MG BASE	N72809 001 MAR 20, 1989

MEPROBAMATE

TABLET; ORAL

	MEPROBAMATE		
AA	BARR	600MG	N84230 001
	@	600MG	N84230 001
	NEURAMATE		
AA	HALSEY	200MG	N14359 002
AA		400MG	N14359 001
	@	200MG	N14359 002
	@	400MG	N14359 001

METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL

		METHADOSE		
AA		MALLINCKRODT	**10MG/ML**	**N17116 002**
AA	+		**10MG/ML**	**N17116 002**

METHYLDOPA

TABLET; ORAL

		METHYLDOPA		
AB		HALSEY	**500MG**	**N71753 001 MAR 28, 1988**
	@		500MG	N71753 001 MAR 28, 1988
AB		NOVOPHARM	**125MG**	**N71105 001 DEC 05, 1986**
AB			**250MG**	**N71106 001 DEC 05, 1986**
AB			**500MG**	**N71067 001 DEC 05, 1986**
	@		125MG	N71105 001 DEC 05, 1986
	@		250MG	N71106 001 DEC 05, 1986
	@		500MG	N71067 001 DEC 05, 1986

METHYLTESTOSTERONE

TABLET; ORAL

		ORETON METHYL		
>ADD>	BP	SCHERING	25MG	N03158 002
>DLT>	@		25MG	N03158 002

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

		METOCLOPRAMIDE HCL		
AB		HALSEY	**EQ 10MG BASE**	**N70906 001 OCT 28, 1986**
	@		EQ 10MG BASE	N70906 001 OCT 28, 1986
AB		SCHERING	**EQ 10MG BASE**	**N70598 001 FEB 02, 1987**

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

		METOCLOPRAMIDE HCL		
	@	SCHERING	EQ 10MG BASE	N70598 001 FEB 02, 1987
AB		SUPERPHARM	**EQ 10MG BASE**	**N70926 001 JUN 26, 1987**
	@		EQ 10MG BASE	N70926 001 JUN 26, 1987

METRONIDAZOLE

TABLET; ORAL

		METRONIDAZOLE		
AB		HALSEY	**250MG**	**N70021 001 APR 02, 1985**
AB			**500MG**	**N70593 001 FEB 27, 1986**
	@		250MG	N70021 001 APR 02, 1985
	@		500MG	N70593 001 FEB 27, 1986
AB		ZENITH GOLDLINE	**250MG**	**N18517 001**
AB			**500MG**	**N18517 002 MAY 05, 1982**
AB		ZENITH LABS	**250MG**	**N18517 001**
AB			**500MG**	**N18517 002 MAY 05, 1982**

MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL

		MEXILETINE HCL		
>ADD>	**AB**	GENEVA PHARMS	**150MG**	**N74450 001 MAY 16, 1996**
>ADD>	**AB**		**200MG**	**N74450 002 MAY 16, 1996**
>ADD>	**AB**		**250MG**	**N74450 003 MAY 16, 1996**

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL

		MONISTAT DUAL-PAK		
	+	JOHNSON RW	2%,200MG	N18888 002 OCT 17, 1988

MINOXIDIL

SOLUTION; TOPICAL

	ROGAINE			
	+ UPJOHN	2%	N19501 001	AUG 17, 1988

NADOLOL

TABLET; ORAL

	NADOLOL			
AB	ZENITH LABS	80MG	N74255 001	JAN 24, 1996
AB		120MG	N74255 002	JAN 24, 1996
AB		160MG	N74255 003	JAN 24, 1996

NAPROXEN

TABLET; ORAL

	NAPROXEN			
AB	BIOCRAFT	250MG	N74216 001	APR 11, 1996
AB		375MG	N74216 002	APR 11, 1996
AB		500MG	N74216 003	APR 11, 1996

NAPROXEN SODIUM

TABLET; ORAL

	NAPROXEN SODIUM			
> ADD > AB	WEST WARD PHARM	EQ 500MG BASE	N74480 001	MAY 14, 1996

> ADD >

TABLET, EXTENDED RELEASE; ORAL

	NAPRELAN			
+	ELAN PHARM	EQ 375MG BASE	N20353 001	JAN 05, 1996
+		EQ 500MG BASE	N20353 002	JAN 05, 1996
+		EQ 750MG BASE	N20353 003	JAN 05, 1996

NEOMYCIN SULFATE

INJECTABLE; INJECTION

	MYCIFRADIN			
AP	+ UPJOHN	EQ 350MG BASE/VIAL	N60477 001	
	NEOMYCIN SULFATE			
AP	PFIZER	EQ 350MG BASE/VIAL	N61084 001	
AP	SQUIBB	EQ 350MG BASE/VIAL	N60366 001	

POWDER; FOR RX COMPOUNDING

	NEO-RX			
AA	PHARMA TEK	100%	N61579 001	
		100%	N61579 001	
	NEOMYCIN SULFATE			
	@ ELKINS SINN	100%	N61698 001	
AA	PADDOCK	100%	N62385 001	JUN 01, 1982

NICOTINE

SPRAY, METERED; NASAL

	NICOTROL			
+	PHARMACIA	0.5MG/INH	N20385 001	MAR 22, 1996

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

	NICORETTE			
+	SMITHKLINE BEECHAM	EQ 2MG BASE	N18612 001	JAN 13, 1984
	NICORETTE DS			
+	SMITHKLINE BEECHAM	EQ 4MG BASE	N20066 001	JUN 08, 1992

NITROFURAZONE

OINTMENT; TOPICAL

	NITROFURAZONE			
AT	AMBIX	0.2%	N86077 001	
	@	0.2%	N86077 001	

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

NITRO-DUR

BX	+	KEY PHARMS	0.1MG/HR	N20145 001 APR 04, 1995	
BX	+		0.2MG/HR	N20145 002 APR 04, 1995	
BX	+		0.4MG/HR	N20145 004 APR 04, 1995	
BX	+		0.6MG/HR	N20145 005 APR 04, 1995	
BX	+		0.8MG/HR	N20145 006 APR 04, 1995	> ADD >

TRANSDERM-NITRO

BX		CIBA	0.1MG/HR	N20144 001 FEB 27, 1996	> ADD >
BX	+		0.1MG/HR	N20144 001 FEB 27, 1996	
BX			0.2MG/HR	N20144 002 FEB 27, 1996	
BX	+		0.2MG/HR	N20144 002 FEB 27, 1996	> DLT >
BX			0.4MG/HR	N20144 003 FEB 27, 1996	> DLT > > ADD >
BX	+		0.4MG/HR	N20144 003 FEB 27, 1996	> ADD >
BX			0.6MG/HR	N20144 004 FEB 27, 1996	
BX	+		0.6MG/HR	N20144 004 FEB 27, 1996	
BX			0.8MG/HR	N20144 005 FEB 27, 1996	
BX	+		0.8MG/HR	N20144 005 FEB 27, 1996	

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

NORTRIPTYLINE HCL

AB		BIOCRAFT	**EQ 10MG BASE**	**N73667 001** APR 11, 1996
AB			**EQ 25MG BASE**	**N73667 002** APR 11, 1996
AB			**EQ 50MG BASE**	**N73667 003** APR 11, 1996
AB			**EQ 75MG BASE**	**N73667 004** APR 11, 1996

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

MYCOLOG-II

AT	+	APOTHECON	**100,000 UNITS/GM;0.1%**	**N60576 002** MAY 01, 1985
	@		100,000 UNITS/GM;0.1%	N60576 002 MAY 01, 1985

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ZOFRAN PRESERVATIVE FREE

	+	GLAXO WELLCOME	EQ 2MG BASE/ML	N20007 003 DEC 10, 1993

OXAZEPAM

TABLET; ORAL

OXAZEPAM

AB		PARKE DAVIS	**15MG**	**N71508 001** FEB 02, 1987
	@		15MG	N71508 001 FEB 02, 1987

OXTRIPHYLLINE

SOLUTION; ORAL

CHOLEDYL

		PARKE DAVIS	100MG/5ML	N09268 012 NOV 27, 1984
	@		100MG/5ML	N09268 012 NOV 27, 1984

SYRUP; ORAL

CHOLEDYL

		PARKE DAVIS	50MG/5ML	N09268 011
	@		50MG/5ML	N09268 011

TABLET, DELAYED RELEASE; ORAL

CHOLEDYL

	+	PARKE DAVIS	100MG	N09268 003
	+		200MG	N09268 007
	@		100MG	N09268 003
	@		200MG	N09268 007

OXYBUTYNIN CHLORIDE

SYRUP; ORAL

	DITROPAN			
AA	+ HOECHST MARION RSSL	5MG/5ML	N18211 001	
	OXYBUTYNIN CHLORIDE			
AA	SILARX	5MG/5ML	N74520 001	MAR 29, 1996

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

	PAXIL				
> DLT >	@ SMITHKLINE BEECHAM	EQ 10MG BASE	N20031 001	DEC 29, 1992	
> DLT >	+	EQ 30MG BASE	N20031 003	DEC 29, 1992	
> DLT >	@	EQ 40MG BASE	N20031 005	DEC 29, 1992	
> DLT >		EQ 10MG BASE	N20031 001	DEC 29, 1992	
> ADD >		EQ 30MG BASE	N20031 003	DEC 29, 1992	
> ADD >	+	EQ 40MG BASE	N20031 005	DEC 29, 1992	

PENTAMIDINE ISETHIONATE

POWDER FOR RECONSTITUTION; INHALATION

	NEBUPENT			
> ADD >	FUJISAWA	600MG/VIAL	N19887 002	MAR 22, 1996

PENTOBARBITAL SODIUM

CAPSULE; ORAL

	SODIUM PENTOBARBITAL			
AA	HALSEY	100MG	N84677 001	
	@	100MG	N84677 001	

PERINDOPRIL ERBUMINE

TABLET; ORAL

	ACEON			
	AMARIC	2MG	N20184 001	DEC 30, 1993

PERINDOPRIL ERBUMINE

TABLET; ORAL

	ACEON			
	AMARIC	4MG	N20184 002	DEC 30, 1993
	+	8MG	N20184 003	DEC 30, 1993
	RHONE POULENC RORER	2MG	N20184 001	DEC 30, 1993
		4MG	N20184 002	DEC 30, 1993
	+	8MG	N20184 003	DEC 30, 1993

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

	PHERAZINE VC			
AA	HALSEY	5MG/5ML;6.25MG/5ML	N88868 001	MAR 02, 1987
	@	5MG/5ML;6.25MG/5ML	N88868 001	MAR 02, 1987

PIROXICAM

CAPSULE; ORAL

	PIROXICAM			
> ADD > AB	DANBURY PHARMA	10MG	N74287 001	MAY 16, 1996
> ADD > AB		20MG	N74287 002	MAY 16, 1996

POLYESTRADIOL PHOSPHATE

INJECTABLE; INJECTION

	ESTRADURIN			
	+ WYETH AYERST	40MG/AMP	N10753 001	
	@	40MG/AMP	N10753 001	

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	POTASSIUM CHLORIDE			
AB	BIOCRAFT	8MEQ	N73531 001	APR 26, 1996

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
POTASSIUM CHLORIDE

AB	BIOCRAFT	10MEQ	N73532 001	APR 26, 1996

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

AP	FUJISAWA	2MEQ/ML	N87787 001	APR 20, 1982
	@	2MEQ/ML	N87787 001	APR 20, 1982

PREDNISOLONE

SYRUP; ORAL
PRELONE

> DLT >	MURO	5MG/5ML	N89654 001	JAN 17, 1989
> DLT >		15MG/5ML	N89081 001	FEB 04, 1986
> DLT >				
> ADD >	+	5MG/5ML	N89654 001	JAN 17, 1989
> ADD >				
> ADD >	+	15MG/5ML	N89081 001	FEB 04, 1986
> ADD >				

PREDNISOLONE ACETATE

SUSPENSION; OPHTHALMIC
PRED FORTE

BX	+ ALLERGAN	1%	N17011 001	

SUSPENSION/DROPS; OPHTHALMIC
PRED FORTE

AB	+ ALLERGAN	1%	N17011 001	

PREDNISONE

TABLET; ORAL
PREDNISONE

AB	SUPERPHARM	5MG	N88865 001	OCT 25, 1984
AB		10MG	N88866 001	OCT 25, 1984

PREDNISONE

TABLET; ORAL
PREDNISONE

AB	SUPERPHARM	20MG	N88867 001	OCT 25, 1984
	@	5MG	N88865 001	OCT 25, 1984
	@	10MG	N88866 001	OCT 25, 1984
	@	20MG	N88867 001	OCT 25, 1984

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCANBID

+	PARKE DAVIS	500MG	N20545 001	JAN 31, 1996
+		1GM	N20545 002	JAN 31, 1996

PROMAZINE HYDROCHLORIDE

TABLET; ORAL
SPARINE

	WYETH AYERST	50MG	N10348 002	
+		100MG	N10348 003	
+		50MG	N10348 002	
@		100MG	N10348 003	

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPHENE 65

AA	HALSEY	65MG	N83538 002	
	@	65MG	N83538 002	

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

BD	HALSEY	50MG	N80015 001	
	@	50MG	N80015 001	

PROTIRELIN

INJECTABLE; INJECTION

	THYPINONE				
AP	+ ABBOTT	0.5MG/ML	N17638 001		
	@	0.5MG/ML	N17638 001		
	THYREL TRH				
AP	FERRING LABS	0.5MG/ML	N18087 001		
	+	0.5MG/ML	N18087 001		

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

	QUINIDINE GLUCONATE				
AB	HALSEY	324MG	N89476 001 APR 10, 1987		
	@	324MG	N89476 001 APR 10, 1987		

QUINIDINE SULFATE

CAPSULE; ORAL

	CIN-QUIN				
AB	SOLVAY	200MG	N85296 001		
		300MG	N85297 001		
		200MG	N85296 001		
	+	300MG	N85297 001		
	QUINIDINE SULFATE				
AB	+ LILLY	200MG	N85103 001		
	@	200MG	N85103 001		

TABLET; ORAL

	QUINIDINE SULFATE				
AB	1ST TX	200MG	N85068 001		
AB	BARR	200MG	N84177 001		
	@	200MG	N84177 001		
AB	HALSEY	200MG	N83583 001		
	@	200MG	N83583 001		
AB	+ LILLY	200MG	N85038 001		
	@	200MG	N85038 001		
AB	ROXANE	200MG	N83640 001		
AB	+	200MG	N83640 001		
AB		300MG	N85632 001	> ADD >	
AB	+	300MG	N85632 001	> ADD >	
	@ SCHERER	200MG	N85068 001	> ADD >	
				> ADD >	
	QUINORA				
AB	+ KEY PHARMS	300MG	N85222 001		

QUINIDINE SULFATE

TABLET; ORAL

	QUINORA		
	@ SCHERING	300MG	N85222 001

RAMIPRIL

CAPSULE; ORAL

	ALTACE		
	HOECHST MARION RSSL	1.25MG	N19901 001 JAN 28, 1991
		2.5MG	N19901 002 JAN 28, 1991
		5MG	N19901 003 JAN 28, 1991
	+	10MG	N19901 004 JAN 28, 1991
	HOECHST ROUSSEL	1.25MG	N19901 001 JAN 28, 1991
		2.5MG	N19901 002 JAN 28, 1991
		5MG	N19901 003 JAN 28, 1991
	+	10MG	N19901 004 JAN 28, 1991

RITONAVIR

CAPSULE; ORAL

	NORVIR		
	+ ABBOTT	100MG	N20680 001 MAR 01, 1996

SOLUTION; ORAL

	NORVIR		
	ABBOTT	80MG/ML	N20659 001 MAR 01, 1996

SELEGILINE HYDROCHLORIDE

CAPSULE; ORAL

	ELDEPRYL		
	+ SOMERSET	5MG	N20647 001 MAY 15, 1996

SELEGILINE HYDROCHLORIDE

>_DLT_>	TABLET; ORAL			
>_DLT_>	ELDEPRYL			
>_DLT_>	+ SOMERSET	5MG	N19334 001 JUN 05, 1989	
>_DLT_>				
>_ADD_>	@	5MG	N19334 001 JUN 05, 1989	
>_ADD_>				

SERTRALINE HYDROCHLORIDE

TABLET; ORAL			
ZOLOFT			
PFIZER	EQ 25MG BASE	N19839 005 MAR 06, 1996	

SODIUM PHENYLBUTYRATE

POWDER; ORAL			
BUPHENYL			
+ UCYCLYD	3GM/TEASPOONFUL	N20573 001 APR 30, 1996	
>_ADD_> TABLET; ORAL			
>_ADD_> BUPHENYL			
>_ADD_> + UCYCLYD	500MG	N20572 001 MAY 13, 1996	
>_ADD_>			

SPIRAPRIL HYDROCHLORIDE

>_DLT_>	TABLET; ORAL			
>_DLT_>	RENORMAX			
>_DLT_>	SANDOZ	3MG	N20240 001 DEC 29, 1994	
>_DLT_>		6MG	N20240 002 DEC 29, 1994	
>_DLT_>		12MG	N20240 003 DEC 29, 1994	
>_DLT_>				
>_DLT_>	+	24MG	N20240 004 DEC 29, 1994	
>_DLT_>				
>_ADD_>	@ SCHERING	3MG	N20240 001 DEC 29, 1994	
>_ADD_>				
>_ADD_>	@	6MG	N20240 002 DEC 29, 1994	
>_ADD_>				
>_ADD_>	@	12MG	N20240 003 DEC 29, 1994	
>_ADD_>				

SPIRAPRIL HYDROCHLORIDE

>_ADD_>	TABLET; ORAL		
>_ADD_>	RENORMAX		
>_ADD_>	@ SCHERING	24MG	N20240 004 DEC 29, 1994
>_ADD_>			

SUCRALFATE

	TABLET; ORAL		
	CARAFATE		
AB	+ BLUE RIDGE	**1GM**	**N18333 001**
	SUCRALFATE		
AB	BIOCRAFT	**1GM**	**N70848 001** MAR 29, 1996

SULFAMETHOXAZOLE; TRIMETHOPRIM

	TABLET; ORAL		
	SULFATRIM-DS		
AB	SUPERPHARM	**800MG;160MG**	**N70066 001 JUN 24, 1985**
	@	800MG;160MG	N70066 001 JUN 24, 1985
	SULFATRIM-SS		
AB	SUPERPHARM	**400MG;80MG**	**N70065 002 JUN 24, 1985**
	@	400MG;80MG	N70065 002 JUN 24, 1985

TAMOXIFEN CITRATE

TABLET; ORAL			
NOLVADEX			
@ ZENECA	EQ 20MG BASE	N17970 002 MAR 21, 1994	
+	EQ 20MG BASE	N17970 002 MAR 21, 1994	

TECHNETIUM TC-99M TETROFOSMIN KIT

INJECTABLE; INJECTION			
MYOVIEW			
MEDI PHYSICS	N/A	N20372 001 FEB 09, 1996	

TERAZOSIN HYDROCHLORIDE

> DLT >		TABLET; ORAL			
> DLT >		HYTRIN			
> DLT >		ABBOTT	EQ 1MG BASE	N19057 001	
> DLT >				AUG 07, 1987	
> DLT >	+		EQ 2MG BASE	N19057 002	
> DLT >				AUG 07, 1987	
> DLT >			EQ 5MG BASE	N19057 003	
> DLT >				AUG 07, 1987	
> DLT >			EQ 10MG BASE	N19057 004	
> DLT >				AUG 07, 1987	
> ADD >	@		EQ 1MG BASE	N19057 001	
> ADD >				AUG 07, 1987	
> ADD >	@		EQ 2MG BASE	N19057 002	
> ADD >				AUG 07, 1987	
> ADD >	@		EQ 5MG BASE	N19057 003	
> ADD >				AUG 07, 1987	
> ADD >	@		EQ 10MG BASE	N19057 004	
> ADD >				AUG 07, 1987	

> ADD > TERBINAFINE HYDROCHLORIDE

> ADD >		TABLET; ORAL			
> ADD >		LAMISIL			
> ADD >	+	SANDOZ	EQ 250MG BASE	N20539 001	
> ADD >				MAY 10, 1996	

TETRACYCLINE HYDROCHLORIDE

		CAPSULE; ORAL			
		TETRACYCLINE HCL			
AB		SUPERPHARM	**250MG**	**N62540 001**	
				MAR 21, 1985	
AB			**500MG**	**N62540 002**	
				MAR 21, 1985	
	@		250MG	N62540 001	
				MAR 21, 1985	
	@		500MG	N62540 002	
				MAR 21, 1985	

THALLOUS CHLORIDE, TL-201

		INJECTABLE; INJECTION			
		THALLOUS CHLORIDE TL 201			
		MEDI PHYSICS	2mCi/ML	N18110 001	
				FEB 01, 1982	

THALLOUS CHLORIDE, TL-201

		INJECTABLE; INJECTION			
		THALLOUS CHLORIDE TL 201			
		MEDI PHYSICS	1mCi/ML	N18110 002	
				FEB 27, 1996	

THEOPHYLLINE

		CAPSULE, EXTENDED RELEASE; ORAL			
		THEOVENT			
BC		SCHERING	125MG	N87010 001	
				JAN 31, 1985	
BC			250MG	N87910 001	
				JAN 31, 1985	
	@		125MG	N87010 001	
				JAN 31, 1985	
	@		250MG	N87910 001	
				JAN 31, 1985	
		INJECTABLE; INJECTION			
		THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER			
AP		MCGAW	**40MG/100ML**	**N19083 001**	
				NOV 07, 1984	
	@		40MG/100ML	N19083 001	
				NOV 07, 1984	
		THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER			
AP		MCGAW	**80MG/100ML**	**N19083 002**	
				NOV 07, 1984	
	@		80MG/100ML	N19083 002	
				NOV 07, 1984	
		THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER			
AP		MCGAW	**160MG/100ML**	**N19083 003**	
				NOV 07, 1984	
	@		160MG/100ML	N19083 003	
				NOV 07, 1984	
		TABLET, EXTENDED RELEASE; ORAL			
		UNI-DUR			
BC	+	KEY PHARMS	600MG	N89823 001	
				JAN 04, 1995	
		UNIPHYL			
BC		PURDUE FREDERICK	600MG	N40086 001	
				APR 15, 1996	

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
THIAMINE HCL

> ADD >	AP	SANOFI WINTHROP	100MG/ML	N40079 001	MAY 03, 1996
> ADD >					

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
MELLARIL

AA		SANDOZ	30MG/ML	N11808 012
AA	+		30MG/ML	N11808 012
AA			100MG/ML	N11808 018
AA	+		100MG/ML	N11808 018

TABLET; ORAL
THIORIDAZINE HCL

AB		SUPERPHARM	10MG	N89103 001 JUL 02, 1985
AB			25MG	N89104 001 JUL 02, 1985
AB			50MG	N89105 001 JUL 02, 1985
	@		10MG	N89103 001 JUL 02, 1985
	@		25MG	N89104 001 JUL 02, 1985
	@		50MG	N89105 001 JUL 02, 1985

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC
AKTOB

AT		AKORN	0.3%	N64096 001 JAN 31, 1996

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

AB		BARR	100MG	N70162 001 JAN 14, 1986
AB			250MG	N70163 001 JAN 14, 1986

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

AB		BARR	500MG	N70164 001 JAN 14, 1986
	@		100MG	N70162 001 JAN 14, 1986
	@		250MG	N70163 001 JAN 14, 1986
	@		500MG	N70164 001 JAN 14, 1986
AB		ZENITH GOLDLINE	100MG	N18894 001 NOV 02, 1984
AB			250MG	N18894 002 NOV 02, 1984
AB			500MG	N18894 003 NOV 02, 1984
AB		ZENITH LABS	100MG	N18894 001 NOV 02, 1984
AB			250MG	N18894 002 NOV 02, 1984
AB			500MG	N18894 003 NOV 02, 1984

TOLBUTAMIDE

TABLET; ORAL
ORINASE

> DLT >				
> DLT >	AB	+ UPJOHN	500MG	N10670 001
> ADD >		@	500MG	N10670 001

TOLBUTAMIDE

	AB	BARR	500MG	N87121 001
		@	500MG	N87121 001
> DLT >	AB	EON LABS	500MG	N12678 001
> ADD >	AB	+	500MG	N12678 001
	AB	SUPERPHARM	500MG	N88893 001 NOV 19, 1984
		@	500MG	N88893 001 NOV 19, 1984

TOLMETIN SODIUM

TABLET; ORAL
TOLMETIN SODIUM

AB		BAKER NORTON	EQ 600MG BASE	N74399 001 MAR 28, 1996

> ADD > TOPOTECAN HYDROCHLORIDE

> ADD > INJECTABLE; INJECTION
> ADD > HYCAMTIN
> ADD > + SMITHKLINE BEECHAM EQ 4MG BASE/VIAL N20671 001
> ADD > MAY 28, 1996

TRANDOLAPRIL

TABLET; ORAL
MAVIK
KNOLL PHARM 1MG N20528 001
APR 26, 1996
2MG N20528 002
APR 26, 1996
\+ 4MG N20528 003
APR 26, 1996

TRETINOIN

CREAM; TOPICAL
RENOVA
JOHNSON RW 0.05% N19963 001
DEC 29, 1995

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
ARISTOCORT A
AT LEDERLE **0.5%** **N80745 003**
AT + LEDERLE LABS **0.5%** **N80745 003**
KENALOG
AT + APOTHECON **0.5%** **N83944 001**
@ 0.5% N83944 001

> ADD > SPRAY, METERED; NASAL
> ADD > NASACORT AQ
> ADD > + RHONE POULENC RORER 0.055MG/INH N20468 001
> ADD > MAY 20, 1996

TRIPROLIDINE HYDROCHLORIDE

> DLT > SYRUP; ORAL
> DLT > TRIPROLIDINE HCL
> DLT > HALSEY 1.25MG/5ML N88735 001
> DLT > JAN 17, 1985

> DLT > TRIPROLIDINE HYDROCHLORIDE

> DLT > SYRUP; ORAL
> DLT > TRIPROLIDINE HCL
> ADD > @ HALSEY 1.25MG/5ML N88735 001
> ADD > JAN 17, 1985

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
VERELAN
\+ ELAN PHARM 360MG N19614 004
MAY 10, 1996

TABLET; ORAL
VERAPAMIL HCL
AB SIDMAK LABS NJ **40MG** **N72751 001**
FEB 23, 1996

TABLET, EXTENDED RELEASE; ORAL
COVERA-HS
BC SEARLE 180MG N20552 001
FEB 26, 1996
BC 240MG N20552 002
FEB 26, 1996

VERAPAMIL HCL
AB MYLAN **240MG** **N74587 001**
MAR 23, 1996
AB SIDMAK LABS NJ **240MG** **N72922 001**
MAR 01, 1996

VIDARABINE

INJECTABLE; INJECTION
VIRA-A
\+ PARKE DAVIS EQ 187.4MG BASE/ML N50523 001
@ EQ 187.4MG BASE/ML N50523 001

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL

8-HOUR BAYER			
+ BAYER	650MG	N16030 001	
+ STERLING	650MG	N16030 001	
MEASURIN			
+ BAYER	650MG	N16030 002	
+ STERLING	650MG	N16030 002	

BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL

DIMETANE		
+ ROBINS AH	8MG	N10799 010 JUN 10, 1983
+	12MG	N10799 011 JUN 10, 1983
@ WHITEHALL ROBINS	8MG	N10799 010 JUN 10, 1983
DIMETAPP		
+ WHITEHALL ROBINS	12MG	N10799 011 JUN 10, 1983

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL

DIMETAPP		
+ ROBINS AH	2MG/5ML;12.5MG/5ML	N13087 003 MAR 29, 1984
+ WHITEHALL ROBINS	2MG/5ML;12.5MG/5ML	N13087 003 MAR 29, 1984

TABLET, EXTENDED RELEASE; ORAL

DIMETAPP		
+ ROBINS AH	12MG;75MG	N12436 003 MAY 14, 1985
+ WHITEHALL ROBINS	12MG;75MG	N12436 003 MAY 14, 1985

BROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

EFIDAC 24 PSEUDOEPHEDRINE HCL/BROMPHENIRAMINE MALEATE		
+ ALZA	16MG;240MG	N19672 001 MAR 29, 1996

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CODIMAL-L.A. 12		
CENT PHARMS	12MG;120MG	N18935 001 APR 15, 1985
+	12MG;120MG	N18935 001 APR 15, 1985
PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE		
+ CENT PHARMS	8MG;120MG	N19428 001 AUG 02, 1988
PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE		
+ GRAHAM	8MG;120MG	N18844 001 MAR 20, 1985
+	12MG;120MG	N18843 001 MAR 18, 1985
@	8MG;120MG	N18844 001 MAR 20, 1985
@	12MG;120MG	N18843 001 MAR 18, 1985
PSEUDOEPHEDRINE HYDROCHLORIDE AND CHLORPHENIRAMINE MALEATE		
CENT PHARMS	8MG;120MG	N19428 001 AUG 02, 1988

IBUPROFEN

CAPSULE; ORAL

PROVEL		
+ SANDOZ	200MG	N20402 001 APR 20, 1995
@	200MG	N20402 001 APR 20, 1995

TABLET; ORAL

IBUPROFEN		
HALSEY	200MG	N71027 001 SEP 29, 1987
@	200MG	N71027 001 SEP 29, 1987
@ LEMMON	200MG	N73141 001 MAY 29, 1992
TAG PHARMS	200MG	N73141 001 MAY 29, 1992

INSULIN PURIFIED BEEF

INJECTABLE; INJECTION
REGULAR ILETIN II

+	LILLY	100 UNITS/ML	N18478 001
@		100 UNITS/ML	N18478 001

INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION
NOVOLIN N

+	NOVO NORDISK	100 UNITS/ML	N19065 001 JAN 23, 1985
@		100 UNITS/ML	N19065 001 JAN 23, 1985

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION
PROTAMINE ZINC INSULIN

+	SQUIBB	40 UNITS/ML	N17928 001
+		100 UNITS/ML	N17928 003
@		40 UNITS/ML	N17928 001
@		100 UNITS/ML	N17928 003

INSULIN ZINC SUSP EXTENDED PURIFIED BEEF

INJECTABLE; INJECTION
ULTRALENTE

				> ADD >
+	NOVO NORDISK	100 UNITS/ML	N18385 001	> ADD >
@		100 UNITS/ML	N18385 001	

INSULIN ZINC SUSP PROMPT PURIFIED PORK

INJECTABLE; INJECTION
SEMILENTE

+	NOVO NORDISK	100 UNITS/ML	N18382 001
@		100 UNITS/ML	N18382 001

INSULIN ZINC SUSP PURIFIED BEEF

INJECTABLE; INJECTION
LENTE ILETIN II

+	LILLY	100 UNITS/ML	N18477 001

INSULIN ZINC SUSP PURIFIED BEEF

INJECTABLE; INJECTION
LENTE ILETIN II

@	LILLY	100 UNITS/ML	N18477 001

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE 7

	NMC	2%	N74164 001 MAR 29, 1996

MICONAZOLE NITRATE

	G AND W LABS	2%	N74366 001 FEB 22, 1996

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MONISTAT-3 COMBINATION PACK

+	ADV CARE	2%,200MG	N20670 002 APR 16, 1996

MINOXIDIL

SOLUTION; TOPICAL
MINOXIDIL (FOR MEN)

	BARRE	2%	N74588 001 APR 05, 1996
	BAUSCH AND LOMB	2%	N74643 001 APR 09, 1996
	COPLEY PHARM	2%	N74500 001 MAY 23, 1996
	LEMMON	2%	N74589 001 APR 05, 1996

ROGAINE (FOR MEN)

+	UPJOHN	2%	N19501 002 FEB 09, 1996

ROGAINE (FOR WOMEN)

+	UPJOHN	2%	N19501 003 FEB 09, 1996

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
OCUHIST

	AKORN	0.025%;0.3%	N20485 001 JAN 31, 1996

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICORETTE
+ SMITHKLINE BEECHAM — EQ 2MG BASE — N18612 002 FEB 09, 1996
+ — EQ 4MG BASE — N20066 002 FEB 09, 1996

> ADD > NIZATIDINE

> ADD > TABLET; ORAL
> ADD > AXID AR
> ADD > + WHITEHALL ROBINS — 75MG — N20555 001 MAY 09, 1996
> ADD >

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
EFIDAC 24 PSEUDOEPHEDRINE HCL
+ CIBA — 240MG — N20021 002 DEC 15, 1992

EFIDAC/24
+ CIBA — 240MG — N20021 002 DEC 15, 1992

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 5 / MAY '96

NO MAY 1996 APPROVALS

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January 1, 1996 thru May 31, 1996]

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Albendazole TN=	Treatment of hydatid disease (cystic echinococcosis due to E. granulosus larvae or alveolar echinococcosis due to E. multilocularis larvae).	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=01/17/96 MA= / /
Albendazole TN=	Treatment of neurocysticercosis due to Taenia solium as: 1) chemotherapy of parenchymal, subarachnoidal and raccmose (cysts in spinal fluid) neurocysticercosis in symptomatic cases and 2) prophylaxis of epilepsy and other sequelae in asymptomatic neurocysticercosis.	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=01/18/96 MA= / /
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive zgomycosis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=05/06/96 MA= / /
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive coccidioidomycosis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=05/06/96 MA= / /
Antihemophilic factor (human) TN= Alphanate	Treatment of von Willebrand's disease.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=01/05/96 MA= / /
Arcitumomab TN= 99m Te-labeled CBA-Scan	Diagnosis and localization of primary, residual, recurrent and metastatic medullary thyroid carcinoma.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=05/10/96 MA= / /
Clostridial collagenase TN=	Treatment of advanced (involutional or residual stage) Dupuytren's disease.	Hurst, L. M.D. & Badalamente, M., Ph.D. State University of New York at Stony Brook School of Medicine Health Sciences Center T18-020 Stony Brook, NY 11794 DD=05/23/96 MA= / /
Collagenase (lyophilized) for injection TN= Plaquase	Treatment of Peyronie's disease.	Advance Biofactures Corporation 35 Wilbur Street Lynbrook, NY 11563 DD=03/12/96 MA= / /
Dihydrotestosterone TN=Androgel-DHT	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/96 MA= / /
Etiocholanedione TN=	Treatment of Prader-Willi syndrome.	SuperGen, Inc. 3158 Des Plains Avenue Suite 10 Des Plains, IL 60018 DD=05/07/96 MA= / /
Indoxuridine TN=	Treatment of nonparenchymatous sarcomas.	NeoPharm, Inc. 225 East Deerpath, Suite 250 Lake Forest, IL 60045 DD=04/08/96 MA= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Interferon beta-la TN=Rebif	Treatment of patients with secondary progressive multiple sclerosis.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/11/96 MA= / /
Lipid/DNA human cystic fibrosis gene TN=	Treatment of cystic fibrosis.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=04/08/96 MA= / /
Liposomal prostaglandin E1 injection TN=	Treatment of acute respiratory distress syndrome.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=04/25/96 MA= / /
Nitazoxanide TN=	Treatment of cryptosporidiosis in HIV-positive and AIDS patients.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=01/05/96 MA= / /
Rifapentine TN=	Prophylactic treatment of Mycobacterium avium complex in patients with acquired immunodeficiency syndrome and a CD4+count less than or equal to 75/mm3.	Marion Merrell Dow Inc. P.O. Box 9627 (Park A) Kansas City, MO 64137 DD=03/12/96 MA= / /
R-VIII SQ TN= REFACTO	For long-term and/or hospital treatment of hemophilia A or for treatment of patients with hemophilia A in connection with surgical procedures.	Pharmacia Inc. P.O. Box 16529 Columbus, OH 43216 DD=02/08/96 MA= / /
Somatropin for injection TN=Serostim	Treatment of children with AIDS-associated failure-to-thrive including AIDS-associated wasting.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/26/96 MA= / /
SU101 TN=	Treatment of ovarian cancer.	Sugen, Inc. 515 Galveston Drive Redwood City, CA 94063 DD=03/12/96 MA= / /
Testosterone TN=Androgel	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/96 MA= / /
Thalidomide TN=Synovir	Treatment of HIV-associated wasting syndrome.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=03/11/96 MA= / /
Valine, isoleucine and leucine TN=VIL	Treatment of hyperphenylalaninemia.	Leas Research Products 4 Brookview Lane Troy, NY 12180 DD=01/05/96 MA= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
ORPHAN DRUG PRODUCT APPROVALS FOR 1996		
Bleomycin sulfate TN=Blenoxane	Treatment of malignant pleural effusion.	Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543 DD=09/17/93 MA=02/20/96
Corticorelin ovine triflutate TN=Acthrel	For use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushings syndrome.	Ferring Laboratories, Inc. 400 Rella Boulevard, Suite 201 Suffern, NY 10901 DD=11/24/89 MA=05/23/96
Daunorubicin citrate liposome injection TN=DaunoXome	Treatment of patients with advanced HIV-associated Kaposi's sarcoma.	NeXstar Pharmaceuticals, Inc. 650 Cliffside Drive San Dimas, CA 91773 DD=05/14/93 MA=04/08/96
Ganciclovir intravitreal implant TN=Vitrasert Implant	Treatment of cytomegalovirus retinitis.	Chiron Vision 500 Iolab Drive Claremont, CA 91711 DD=06/07/95 MA=03/04/96
Respiratory syncytial virus immune globulin (human) TN=Respigam	Prophylaxis of respiratory syncytial virus lower respiratory tract infections in infants and young children at high risk of RSV diesase.	MedImmune, Inc. 35 West Watkins Mill Road Gaithersburg, MD 20878 DD=09/27/90 MA=01/18/96
Sodium phenylutyrate TN=Buphenyl	Treatment of urea cycle disorders carbamylphosphate synthetase deficiency, ornithine transcarbamylase deficiency, and arginiosuccinic acid synthetase deficiency	Ucyclyd Pharma 10819 Gilroy Road, Suite 100 Hunt Valley, MD 21031 DD=11/22/93 MA=04/30/96

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

NO MAY 1996 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTING. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE (HFD-650, MPN-2 ROOM 279) 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 16TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

CLOZAPINE *IN VITRO* AND *IN VIVO* (TABLET)	NOV 15, 1995	APR 19, 1996

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

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) OR (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 1-23, PARK BUILDING, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 16TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP1	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP2	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	500MG 50MG 40MG 10MG	95 P-0279/ CP3	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	500MG 50MG 40MG 7.5MG	95 P-0279/ CP4	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP1	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP2	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08. 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP3	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP4	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 5MG	95 P-0278/ CP1	MIKART	NEW STRENGTH	APPROVED MAY 28, 1996

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACYCLOVIR SODIUM INJECTABLE; INJECTION	EQ 5MG BASE/ML (100ML/CONTAINER) (200ML/CONTAINER)	95 P-0268/ CP1	WILMER, CUTLER, & PICKERING	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 27, 1996
ASPIRIN; BUTALBITAL CAPSULE; ORAL	650MG 50MG	96 P-0021/ CP1	SAVAGE	NEW DOSAGE FORM	APPROVED APR 19, 1996
ATRACURIUM BESYLATE INJECTABLE; INJECTION	0.5MG/ML 1MG/ML (100ML CONTAINER)	95 P-0372/ CP1	ABBOTT	NEW STRENGTH	APPROVED MAR 08, 1996
CARBIDOPA; LEVODOPA POWDER FOR RECONSTITUTION; ORAL	25MG/PACKET 100MG/PACKET	95 P-0100/ CP1	ATHENA	NEW DOSAGE FORM	APPROVED MAY 28, 1996
CARBIDOPA; LEVODOPA POWDER FOR RECONSTITUTION; ORAL	25MG/PACKET 250MG/PACKET	95 P-0100/ CP1	ATHENA	NEW DOSAGE FORM	APPROVED MAY 28, 1996
CHOLESTYRAMINE TABLET, CHEWABLE; ORAL	EQ 2GM RESIN	95 P-0277/ CP1	MAYRAND	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 27, 1996
DILTIAZEM HYDROCHLORIDE INJECTABLE, INJECTION	5MG/ML (25ML/SYRINGE) (50ML/SYRINGE)	95 P-0196/ CP1	INTL MEDICATION	NEW STRENGTH	APPROVED FEB 27, 1996
EPINEPHRINE INJECTABLE; SUBCUTANEOUS	0.3MG/DELIVERY	95 P-0190/ CP1	SENETCK PLC	NEW ROUTE OF ADMINISTRATION	APPROVED FEB 15, 1996
HYDROCORTISONE BUTYRATE LOTION; TOPICAL	0.1%	95 P-0223/ CP1	MCKENNA & CUNEO	NEW DOSAGE FORM	APPROVED FEB 21, 1996
LACTULOSE CRYSTALS, FOR RECONSTITUTION; ORAL	20GM/PACKET	95 P-0287/ CP1	BENNETT	NEW DOSAGE FORM NEW STRENGTH	APPROVED APR 19, 1996
MEPERIDINE HYDROCHLORIDE INJECTABLE; INJECTION	10MG/ML (60ML/SYRINGE)	95 P-0348/ CP1	MALLINCKRODT	NEW STRENGTH	APPROVED MAR 08, 1996
METRONIDAZOLE LOTION; TOPICAL	0.75%	95 P-0328/ CP1	RNB PHARM	NEW DOSAGE FORM	APPROVED FEB 23, 1996
NIFEDIPINE CAPSULE, EXTENDED RELEASE; ORAL	30MG 60MG 90MG	95-P-0326/ CP1	KV	NEW DOSAGE FORM	APPROVED FEB 23, 1996
PACLITAXEL INJECTABLE; INJECTION	6MG/ML (16.7ML/VIAL) (33.3ML/VIAL) (50ML/VIAL)	95 P-0360/ CP1	ABBOTT	NEW STRENGTH	APPROVED APR 29, 1996

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 16TH 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-29 INCREASE OF CUMULATIVE DOSE TO 0.3MMOL/KG FOR MRI OF THE CNS IN ADULTS
D-30 5000 IU DOSE FOR PHOPHYLAXIS AGAINST DEEP VEIN THROMBOSIS

NEW INDICATION

I-141 TREATMENT OF HEMODYNAMICALLY STABLE PATIENTS WITHIN 24 HOURS OF ACUTE MYOCARDIAL INFARCTION TO IMPROVE SURVIVAL
I-142 LOCALIZE MYOCARDIAL ISCHEMIA (REVERSIBLE DEFECT) AND INFARCTION (NON-REVERSIBLE DEFECTS) IN EVALUATING MYOCARDIAL FUNCTION
I-143 EPISODIC TREATMENT OF RECURRENT GENITAL HERPES IN IMMUNOCOMPETENT ADULTS
I-144 ENHANCEMENT OF MRI OF THE ADULT BODY INTERNAL ORGANS
I-145 0.1MMOL/KG AS A SINGLE INTRAVENOUS BOLUS FOR MRI OF THE CNS IN CHILDREN
I-146 CONTRAST ENHANCEMENT AND FACILITATION OF VISUALIZATION OF EXTRACRANIAL HEAD AND NECK LESIONS
I-147 PREVENTION OF GALLSTONE FORMATION IN OBESE PATIENTS EXPERIENCING RAPID WEIGHT LOSS
I-148 TREATMENT OF ACUTE PNEUMOCYSTIC CARINII PNEUMONIA (PCP) IN HIV-INFECTED PATIENTS WHOSE ALVEOLAR-ARTERIAL OXYGEN DIFFERENCE ($AaDO_2$) iS LESS THAN OR EQUAL TO 55 TORR
I-149 TREATMENT OF PATIENTS WITH NON-SMALL CELL LUNG CANCER
I-150 TREATMENT OF OBSESSIVE COMPULSIVE DISORDER AND PANIC DISORDER
I-151 PREVENTION OF AND PREVENTION OF FURTHER POSTOPERATIVE NAUSEA AND VOMITING IN PEDIATRIC PATIENTS RECEIVING GENERAL ANESTHESIA

PATENT USE CODE

U-121 METHOD OF TREATING CONDITIONS MEDIATED THROUGH HISTAMINE H2-RECEPTORS
U-122 A THERAPEUTIC METHOD FOR CONTROLLING THROMBOSIS
U-123 METHOD FOR CONTROLLING THROMBOSIS AND DECREASING BLOOD HYPERCOAGULATION AND HEMORRHAGING RISKS
U-124 TREATMENT OF ACNE
U-125 TREATING NEUROGENERATIVE DISEASES
U-126 TREATMENT OF GASTRITIS
U-127 METHOD OF PRODUCING NEUROMUSCULAR BLOCKADE
U-128 METHODS FOR TREATMENT OF TUMORS
U-129 METHOD TO DESTROY OR IMPAIR TARGET CELLS
U-130 MANAGEMENT OF PATIENTS WITH MASTOCYTOSIS
U-131 PHOTODAMAGED SKIN
U-132 INHIBITING HIV PROTEASE
U-133 MANAGEMENT OF OBESITY INCLUDING WEIGHT LOSS AND MAINTENANCE IN PATIENTS ON A REDUCED-CALORIE DIET
U-134 TREATMENT OF ACNE VULGARIS
U-135 ANTITUMOR AGENT
U-136 PROCESS FOR WASTE NITROGEN REMOVAL

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19806 001	ACRIVASTINE; SEMPREX-D	4650807	MAR 26, 2008	U-93		
>ADD>	20338 001	ADAPALENE; DIFFERIN	4717720	APR 10, 2006	U-134	NCE	MAY 31, 2001
>ADD>	20380 001	ADAPALENE; DIFFERIN	4717720	APR 10, 2006	U-134	NCE	MAY 31, 2001
	20221 001	AMIFOSTINE; ETHYOL				I-149	MAR 15, 1999
	20541 001	ANASTROZOLE; ARIMIDEX	4935437	JUN 10, 2008			
	20428 001	AZELAIC ACID; AZELEX	4386104	MAY 31, 2000	U-124		
	20498 001	BICALUTAMIDE; CASODEX	4636505	JAN 13, 2004			
	50443 001	BLEOMYCIN SULFATE; BLENOXANE				ODE	FEB 20, 2003
>ADD>	19672 001	BROMPHENIRAMINE MALEATE; EFIDAC 24	4810502	MAR 14, 2006			
>ADD>			4801461	MAR 14, 2006			
>ADD>			4673405	MAR 18, 2003			
>ADD>			4662880	MAR 14, 2006			
>ADD>	18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	MAY 22, 2000	U-13		
>ADD>			5015646	MAY 14, 2008			
>DLT>			~~5015646~~	~~MAY 14, 2008~~	~~U-13~~		
>ADD>	18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	MAY 22, 2000	U-13		
>ADD>			5015646	MAY 14, 2008			
>DLT>			~~5015646~~	~~MAY 14, 2008~~	~~U-13~~		
	20421 001	BUTOCONAZOLE NITRATE; FEMSTAT 3	4078071	JUL 28, 1997			
	20273 001	CALCIPOTRIENE; DOVONEX				NP	DEC 21, 1998
	20313 002	CALCITONIN, SALMON; MIACALCIN	4866048	DEC 29, 2007	U-88	NCE	DEC 29, 1998
	18874 001	CALCITRIOL; CALCIJEX	4344949	OCT 03, 2000			
	18874 002	CALCITRIOL; CALCIJEX	4308264	JAN 28, 2001			
	18343 004	CAPTOPRIL; CAPOTEN	4308264	JAN 28, 2001			
						I-95	SEP 23, 1996
	18343 007	CAPTOPRIL; CAPOTEN				I-101	JAN 28, 1997
						I-95	SEP 23, 1996
	20234 001	CARBAMAZEPINE; TEGRETOL-XR				I-101	JAN 28, 1997
			5284662	FEB 08, 2011			
	20234 002	CARBAMAZEPINE; TEGRETOL-XR	RE34990	JUL 29, 2007			
			5284662	FEB 08, 2011			
	20234 003	CARBAMAZEPINE; TEGRETOL-XR	RE34990	JUL 29, 2007			
			5284662	FEB 08, 2011			
	19835 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	RE34990	JUL 29, 2007			
	19835 002	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
	20398 001	CISAPRIDE MONOHYDRATE; PROPULSID	4525358	JUN 25, 2002			
			4962115	OCT 09, 2007	U-79	NCE	JUL 29, 1998

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20551 001	CISATRACURIUM BESYLATE; NIMBEX	5453510	SEP 26, 2012	U-127		
			4179507	DEC 18, 1996	U-127		
	20551 002	CISATRACURIUM BESYLATE; NIMBEX PRESERVATIVE FREE	5453510	SEP 26, 2012	U-127		
			4179507	DEC 18, 1996	U-127		
	20551 003	CISATRACURIUM BESYLATE; NIMBEX PRESERVATIVE FREE	5453510	SEP 26, 2012	U-127		
			4179507	DEC 18, 1996	U-127		
						NCE	MAY 23, 2001
>ADD>	20162 001	CORTICORELIN OVINE TRISULFATE; ACTHREL	4515805	MAY 07, 2002	U-130		
	20479 001	CROMOLYN SODIUM; GASTROCROM	4421762	DEC 20, 2000	U-130		
	20287 001	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2005		NCE	DEC 22, 1999
						D-30	MAR 18, 1999
	20287 003	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2005		NCE	DEC 22, 1999
						D-30	MAR 18, 1999
						ODE	APR 08, 2003
	50704 002	DAUNORUBICIN CITRATE; DAUNOXOME	4762856	FEB 02, 2007	U-67	NCE	SEP 18, 1997
	20118 001	DESFLURANE; SUPRANE	5047398	SEP 10, 2008			
	19955 001	DESMOPRESSIN ACETATE; DDAVP	5047398	SEP 10, 2008			
	19955 002	DESMOPRESSIN ACETATE; DDAVP	4309445	JUN 16, 2000	U-133		
	20344 001	DEXFENFLURAMINE HYDROCHLORIDE; REDUX				NDF	MAR 08, 1999
	20254 001	DICLOFENAC SODIUM; VOLTAREN-XR					
>ADD>	20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
>ADD>	20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
>ADD>	20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
	18723 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
	18723 002	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
	18723 003	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
>ADD>	20449 001	DOCETAXEL; TAXOTERE	4814470	JUL 14, 2007		NCE	MAY 14, 2001
	20164 001	ENOXAPARIN SODIUM; LOVENOX	5389618	FEB 14, 2012			
			4692435	DEC 24, 2004	U-123		
			4486420	DEC 04, 2001	U-122		
	20472 001	ESTRADIOL; ESTRING				NDF	APR 26, 1999
>ADD>	20457 001	ETOPOSIDE PHOSPHATE; ETOPOPHOS	5041424	AUG 20, 2008	U-135		
>ADD>			4904768	FEB 27, 2007		NE	MAY 17, 1999
	20195 007	FENTANYL CITRATE; FENTANYL	4671953	JUN 09, 2004	U-87	NDF	OCT 04, 1996
	20548 001	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
	20548 002	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
	20548 003	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20235 001	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
	20235 002	GABAPENTIN; NEURONTIN	4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
			5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
	20235 003	GABAPENTIN; NEURONTIN	4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
			5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
	20123 001	GADODIAMIDE; OMNISCAN	4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
			4687659	MAY 04, 2007		D-29	FEB 05, 1999
						I-145	FEB 05, 1999
	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST				I-144	FEB 05, 1999
	20569 001	GANCICLOVIR; VITRASERT	4647447	MAR 03, 2004		I-146	FEB 28, 1999
>ADD>	20509 001	GEMCITABINE HYDROCHLORIDE; GEMZAR				NP	MAR 04, 1996
>ADD>	20509 002	GEMCITABINE HYDROCHLORIDE; GEMZAR				NCE	MAY 15, 2001
>ADD>	19726 001	GOSERELIN ACETATE; ZOLADEX				NCE	MAY 15, 2001
>ADD>			5366734	NOV 22, 2011			
	20578 001	GOSERELIN ACETATE; ZOLADEX	4767628	AUG 30, 2005		I-88	FEB 02, 1996
			5366734	NOV 22, 2011			
			4767628	AUG 30, 2005			
			4100274	APR 22, 1999		NP	JAN 11, 1999
	20239 001	GRANISETRON HYDROCHLORIDE; KYTRIL				NP	JAN 11, 1999
	20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-89		
	19836 001	HISTRELIN ACETATE; SUPPRELIN	4886808	DEC 29, 2007	U-105		
	19836 002	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
	19836 003	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
	20685 001	INDINAVIR SULFATE; CRIXIVAN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
	20685 003	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
	20351 001	IODIXANOL; VISIPAQUE 270	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
			5349085	SEP 20, 2011		NCE	MAR 22, 2001
	20351 002	IODIXANOL; VISIPAQUE 320	4396597	JUL 03, 1999			
			4278654	JUL 03, 1999			
			5349085	SEP 20, 2011		NCE	MAR 22, 2001
	20564 001	LAMIVUDINE; EPIVIR	4396597	JUL 03, 1999			
	20596 001	LAMIVUDINE; EPIVIR	4278654	JUL 03, 1999			
			5047407	FEB 08, 2009			
			5047407	FEB 08, 2009			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20241 001	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
>DLT>	~~20241 001~~	~~LAMOTRIGINE; LAMICTAL~~	~~4602017~~	~~JUL 22, 2003~~	~~U-106~~	~~NCE~~	~~DEC 27, 1999~~
>ADD>	20241 002	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
>DLT>	~~20241 002~~	~~LAMOTRIGINE; LAMICTAL~~	~~4602017~~	~~JUL 22, 2003~~	~~U-106~~	~~NCE~~	~~DEC 27, 1999~~
>ADD>	20241 003	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
>DLT>	~~20241 003~~	~~LAMOTRIGINE; LAMICTAL~~	~~4602017~~	~~JUL 22, 2003~~	~~U-106~~	~~NCE~~	~~DEC 27, 1999~~
>ADD>	20241 004	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
>DLT>	~~20241 004~~	~~LAMOTRIGINE; LAMICTAL~~	~~4602017~~	~~JUL 22, 2003~~	~~U-106~~	~~NCE~~	~~DEC 27, 1999~~
>ADD>	20241 005	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
>DLT>	~~20241 005~~	~~LAMOTRIGINE; LAMICTAL~~	~~4602017~~	~~JUL 22, 2003~~	~~U-106~~	~~NCE~~	~~DEC 27, 1999~~
>ADD>	20241 006	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
>DLT>	~~20241 006~~	~~LAMOTRIGINE; LAMICTAL~~	~~4602017~~	~~JUL 22, 2003~~	~~U-106~~	~~NCE~~	~~DEC 27, 1999~~
	20406 001	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126	I-116	APR 08, 1999
	20406 002	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126	I-116	APR 08, 1999
	20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4369184	DEC 02, 2004		NCE	NOV 10, 1998
>ADD>	20517 001	LEUPROLIDE ACETATE; LUPRON DEPOT	5480656	JAN 02, 2013			
>ADD>	20575 001	LIDOCAINE; LIDOCAINE	5332576	JUL 26, 2011			
>ADD>			5234957	FEB 27, 2011		NDF	MAY 21, 1999
>ADD>	20575 002	LIDOCAINE; LIDOCAINE	5332576	JUL 26, 2011			
>ADD>			5234957	FEB 27, 2011		NDF	MAY 21, 1999
	19558 001	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19558 002	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19558 003	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19558 004	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19558 006	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19777 001	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19777 002	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19777 003	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19777 004	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19777 005	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19940 001	MASOPROCOL; ACTINEX	4695590	APR 17, 2008			
>ADD>	20670 002	MICONAZOLE NITRATE; MONISTAT-3 COMBINATION PACK				NP	APR 16, 1999
	20312 001	MOEXIPRIL HYDROCHLORIDE; UNIVASC	4344949	OCT 03, 2000			
	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	JUN 11, 2011			
	20353 001	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999
	20353 002	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999
	20353 003	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20152 001	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003		NCE	DEC 22, 1999
>DLT>	~~20152 001~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 002	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003		NCE	DEC 22, 1999
>DLT>	~~20152 002~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 003	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003		NCE	DEC 22, 1999
>DLT>	~~20152 003~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 004	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003		NCE	DEC 22, 1999
>DLT>	~~20152 004~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 005	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003		NCE	DEC 22, 1999
>DLT>	~~20152 005~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 006	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003		NCE	DEC 22, 1999
>DLT>	~~20152 006~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
	20165 001	NICOTINE; NICODERM	5508038	APR 16, 2013			
	20165 002	NICOTINE; NICODERM	5508038	APR 16, 2013			
	20165 003	NICOTINE; NICODERM	5508038	APR 16, 2013			
	20385 001	NICOTINE; NICOTROL					
>ADD>	20555 001	NIZATIDINE; AXID AR				NP	MAR 22, 1999
	19810 001	OMEPRAZOLE; PRILOSEC				NS	MAY 09, 1999
	19810 003	OMEPRAZOLE; PRILOSEC	4255431	APR 05, 2001	U-108	I-23	MAR 22, 1999
>ADD>	20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4853230	APR 20, 2007	U-108	I-23	MAR 22, 1999
	18841 004	OXAPROZIN; DAYPRO				I-151	MAY 16, 1999
>ADD>	20031 001	PAROXETINE HYDROCHLORIDE; PAXIL				NCE	OCT 29, 1999*
>ADD>	20031 002	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
>ADD>	20031 003	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
>ADD>	20031 004	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
>ADD>	20031 005	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
	19887 002	PENTAMIDINE ISETHIONATE; NEBUPENT				I-150	MAR 07, 1999
	20184 001	PERINDOPRIL ERBUMINE; ACEON				I-148	MAR 05, 1999
	20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
			4508729	AUG 21, 2006			

* - In accordance with section 2105(c) of the FDA Export Reform and Enhancement Act of 1996 (Public Law 104-134)

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20451 001	PORFIMER SODIUM; PHOTOFRIN	5438071	AUG 01, 2012			
		5145863	JUN 12, 2007	U-129	ODE	DEC 27, 2002
		5028621	MAR 10, 2004			
		4932934	JUN 12, 2007	U-128	NCE	DEC 27, 2000
		4866168	MAR 10, 2004			
		4649151	MAR 10, 2004			
					ODE	DEC 27, 2002
19898 006	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008			
		5030447	JUL 09, 2008			
		4346227	OCT 20, 2005			
19898 007	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008			
		5030447	JUL 09, 2008			
		4346227	OCT 20, 2005			
20545 001	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 1999
20545 002	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 1999
19885 001	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
19885 002	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
19885 003	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
19885 004	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
19593 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	MAY 11, 2004			
		4521431	JUN 04, 2002	U-121		
		4128658	JUL 25, 1997	U-121		
19593 002	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	MAY 11, 2004			
		4521431	JUN 04, 2002	U-121		
		4128658	JUL 25, 1997	U-121		
20520 001	RANITIDINE HYDROCHLORIDE; ZANTAC 75	4880636	MAY 13, 2008			
		4521431	JUN 04, 2002	U-121		
		4128658	JUL 25, 1997	U-121		
20272 001	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20272 002	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20272 003	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20272 004	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20272 005	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20659 001	RITONAVIR; NORVIR	5484801	JAN 28, 2014		NCE	MAR 01, 2001
20680 001	RITONAVIR; NORVIR				NCE	MAR 01, 2001
20628 001	SAQUINAVIR MESYLATE; INVIRASE	5196438	NOV 19, 2010			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

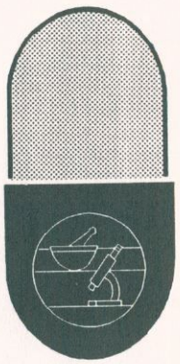
	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL	5242950	APR 23, 2012		ODE	JUN 05, 1996
			5151419	SEP 29, 2009			
			4880833	NOV 14, 2006			
>ADD>	20572 001	SODIUM PHENYLBUTYRATE; BUPHENYL	4457942	AUG 20, 2002	U-136	NCE	APR 30, 2001
>ADD>	20573 001	SODIUM PHENYLBUTYRATE; BUPHENYL	4457942	AUG 20, 2002	U-136	NCE	APR 30, 2001
	20280 004	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998
	20280 006	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998
>ADD>	20240 001	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
>DLT>	~~20240 001~~	~~SPIRAPRIL HYDROCHLORIDE; RENORMAX~~	~~4470972~~	~~SEP 11, 2001~~	~~U-3~~	~~NCE~~	~~DEC 29, 1999~~
>ADD>	20240 002	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
>DLT>	~~20240 002~~	~~SPIRAPRIL HYDROCHLORIDE; RENORMAX~~	~~4470972~~	~~SEP 11, 2001~~	~~U-3~~	~~NCE~~	~~DEC 29, 1999~~
>ADD>	20240 003	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
>DLT>	~~20240 003~~	~~SPIRAPRIL HYDROCHLORIDE; RENORMAX~~	~~4470972~~	~~SEP 11, 2001~~	~~U-3~~	~~NCE~~	~~DEC 29, 1999~~
>ADD>	20240 004	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
>DLT>	~~20240 004~~	~~SPIRAPRIL HYDROCHLORIDE; RENORMAX~~	~~4470972~~	~~SEP 11, 2001~~	~~U-3~~	~~NCE~~	~~DEC 29, 1999~~
	20412 001	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	20412 002	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	20412 003	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	20412 004	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	20412 005	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
>ADD>	20256 001	TECHNETIUM TC-99M BICISATE KIT; NEUROLITE	5279811	NOV 23, 2008	U-101	NCE	NOV 23, 1999
>DLT>	~~20256 001~~	~~TECHNETIUM TC-99M BICISATE KIT; NEUROLITE~~	~~5279811~~	~~MAR 18, 2008~~	~~U-101~~	~~NCE~~	~~NOV 23, 1999~~
	19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE				I-142	DEC 14, 1998
	20372 001	TECHNETIUM TC-99M TETROFOSMIN KIT; MYOVIEW	5045302	APR 10, 2007		NCE	FEB 09, 2001
	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
	20347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
	20347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
	20347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
	20347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
>ADD>	20539 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	4755534	JUL 05, 2005	U-73	NDF	MAY 10, 1999
>ADD>						NCE	DEC 30, 1999

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20489 001	TESTOSTERONE; ANDRODERM	5164190	NOV 17, 2008			
			5152997	OCT 06, 2009			
			4983395	JAN 08, 2009			
			4863970	SEP 05, 2006			
			4855294	AUG 08, 2006			
			4849224	JUL 18, 2006		NS	SEP 29, 1998
>ADD>	20671 001	TOPOTECAN HYDROCHLORIDE; HYCAMTIN	5004758	APR 02, 2008		NCE	MAY 28, 2001
	20528 001	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
	20528 002	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
	20528 003	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
	19963 001	TRETINOIN; RENOVA	4877805	OCT 31, 2006	U-131		
			4603146	JUL 29, 2003	U-131		
			4423041	DEC 27, 2000		NP	DEC 29, 1998
	19594 002	URSODIOL; ACTIGALL				I-149	MAR 29, 1999
	20487 001	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 1998
	20487 002	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 1998
	20151 001	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 002	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 003	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 004	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 005	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 006	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5190765	AUG 14, 2007			
			5160744	JUN 27, 2011			
			4753802	MAR 19, 2006			
			4252338	JUN 27, 2011		NP	FEB 26, 1999
	20552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5190765	AUG 14, 2007			
			5160744	JUN 27, 2011			
			4753802	MAR 19, 2006			
			4252338	JUN 27, 2011		NP	FEB 26, 1999

*U.S. Government Printing Office: 1996 - 404-907/20012

New 16th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

Superintendent of Documents Subscription Order Form

Order Processing Code
*** 7809**

Charge your order. It's easy!

MasterCard VISA

☐ **Yes,** enter my subscription as follows:

__ subscriptions of **APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS**, ADP, and the monthly Cumulative Supplements, for $72.00 per year.

The total cost of my order is $_____. Price includes regular shipping and handling and is subject to change. International customers please add 25%.

For privacy protection, check the box below:

☐ Do not make my name available to other mailers.

Please choose method of payment:

☐ Check payable to Superintendent of Documents
☐ GPO Deposit Account ☐☐☐☐☐☐☐ – ☐
☐ VISA or MasterCard
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

_____
(Credit card expiration date)

Thank you for your order!

_____
(Authorizing Signature)

(10/95)

_____
Company or personal name

_____
Additional address/attention line

_____
Street address

_____
City, State, ZIP Code

(_____) _____
Daytime phone including area code

_____
Purchase Order No. (optional)

Mail To: Superintendent of Documents, Government Printing Office, P.O. Box 371954 Pittsburgh, PA 15250-7954
To **FAX** your charge order, call (202) 512-2250.
To charge your subscription call (202) 512-1800.