CUMULATIVE
SUPPLEMENT 3
JAN'96-MAR'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
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Center for Drug Evaluation and Research, FDA

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CONTENTS

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CUMULATIVE SUPPLEMENT 3
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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)
BOEHRINGER MANNHEIM PHARMACEUTICALS CORP (BOEHRINGER MANNHEIM)	BOEHRINGER MANNHEIM CORPORATION THERAPEUTICS DIVISION (BOEHRINGER MANNHEIM)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
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; Prescription and OTC Drug Product Patent and Exclusivity Data; 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. Additionally, the Patent and Exclusivity Data for the Prescription and OTC Drug Products are updated monthly on Internet. 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			
SINGLE SOURCE	2217 (23.9%)			
MULTISOURCE	7069 (76.1%)			
THERAPEUTICALLY EQUIVALENT	6437 (69.3%)			
NOT THERAPEUTICALLY EQUIVALENT	440 (4.7%)			
EXCEPTIONS[1]	192 (2.1%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	586			

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

ACETAMINOPHEN; BUTALBITAL; CAPSULE; ORAL

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; TABLET; ORAL

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

ACETAMINOPHEN; CODEINE PHOSPHATE; TABLET; ORAL

		ACETAMINOPHEN AND CODEINE PHOSPHATE		
>DLT<	**AA**	GENEVA PHARMS	**300MG;30MG**	**N85291 002**
>DLT<	**AA**		**300MG;60MG**	**N85964 001**
>ADD<	@		300MG;30MG	N85291 002
>ADD<	@		300MG;60MG	N85964 001
>DLT<	**AA**	HALSEY	**300MG;60MG**	**N86549 001**
>ADD<	@		300MG;60MG	N86549 001
	AA	MIKART	**300MG;30MG**	**N89238 001**
				FEB 25, 1986
	AA		**300MG;60MG**	**N89244 001**
				FEB 25, 1986
		ACETAMINOPHEN AND CODEINE PHOSPHATE #3		
	AA	MIKART	**300MG;30MG**	**N89238 001**
				FEB 25, 1986
>DLT<	**AA**	SUPERPHARM	**300MG;30MG**	**N89184 001**
>DLT<				OCT 18, 1985
>ADD<	@		300MG;30MG	N89184 001
>ADD<				OCT 18, 1985
		ACETAMINOPHEN AND CODEINE PHOSPHATE #4		
	AA	MIKART	**300MG;60MG**	**N89244 001**
				FEB 25, 1986
>DLT<	**AA**	SUPERPHARM	**300MG;60MG**	**N89185 001**
>DLT<				OCT 18, 1985
>ADD<	@		300MG;60MG	N89185 001
>ADD<				OCT 18, 1985
>DLT<		**ACETAMINOPHEN W/ CODEINE PHOSPHATE**		
>DLT<	**AA**	HALSEY	**300MG;15MG**	**N83871 001**
>DLT<	**AA**		**300MG;30MG**	**N83872 001**
>ADD<	@		300MG;15MG	N83871 001
>ADD<	@		300MG;30MG	N83872 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE; TABLET; ORAL

		HYDROCODONE BITARTRATE AND ACETAMINOPHEN		
>ADD<	**AA**	ROYCE LABS	**500MG;2.5MG**	**N40123 003**
>ADD<				MAR 04, 1996
>ADD<	**AA**		**500MG;5MG**	**N40122 001**
>ADD<				MAR 04, 1996
>ADD<	**AA**		**500MG;7.5MG**	**N40123 004**
>ADD<				MAR 04, 1996
>ADD<	**AA**		**650MG;7.5MG**	**N40123 001**
>ADD<				MAR 04, 1996
>ADD<	**AA**		**650MG;10MG**	**N40123 002**
>ADD<				MAR 04, 1996
>ADD<	**AA**		**750MG;7.5MG**	**N40122 002**
>ADD<				MAR 04, 1996
	AA	VINTAGE PHARMS	**500MG;7.5MG**	**N40144 001**
				FEB 22, 1996
	AA		**650MG;10MG**	**N40143 001**
				FEB 22, 1996
		LORTAB		
		UCB PHARMA	500MG;10MG	N40100 001
				JAN 26, 1996

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE; TABLET; ORAL

		PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN		
>DLT<	**AB**	SUPERPHARM	**650MG;100MG**	**N71319 001**
>DLT<				JAN 06, 1987
>ADD<	@		650MG;100MG	N71319 001
>ADD<				JAN 06, 1987

AMINOPHYLLINE; TABLET; ORAL

		AMINOPHYLLINE		
>DLT<	@	PHOENIX LABS NY	100MG	N85409 001
>DLT<	@		200MG	N85410 001
>ADD<	@	VINTAGE PHARMS	100MG	N85409 001
>ADD<	@		200MG	N85410 001

AMITRIPTYLINE HYDROCHLORIDE; TABLET; ORAL

		AMITRIPTYLINE HCL		
>DLT<	BP	HALSEY	25MG	N85922 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

>ADD>	@ HALSEY	25MG	N85922 001	

AMOXICILLIN

TABLET, CHEWABLE; ORAL
AMOXICILLIN

AB	CLONMEL HLTH CARE	**125MG**	**N64139 001**	
			JAN 29, 1996	
AB		**250MG**	**N64139 002**	>DLT>
			JAN 29, 1996	>DLT>
				>DLT>
				>ADD>
				>ADD>

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL
AUGMENTIN '875'

+	SMITHKLINE BEECHAM	875MG;EQ 125MG BASE	N50720 001	
			FEB 13, 1996	
				>DLT>
				>DLT>
				>DLT>
				>ADD>
				>ADD>
				>DLT>
				>DLT>
				>ADD>

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

>ADD>				
>ADD>				
>ADD>	+ 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**	

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

POWDER FOR RECONSTITUTION; ORAL
POLYCILLIN-PRB

@ APOTHECON	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**	>DLT>
			DEC 01, 1986	>DLT>
				>DLT>
	@	325MG;50MG;40MG	N89448 001	>ADD>
			DEC 01, 1986	>ADD>

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
LOGEN

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

AZATHIOPRINE

TABLET; ORAL
AZATHIOPRINE

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

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
BLENOXANE

+	BRISTOL	EQ 15 UNITS BASE/VIAL	N50443 001
+	BRISTOL MYERS SQUIBB	EQ 15 UNITS BASE/VIAL	N50443 001

BUTABARBITAL SODIUM

ELIXIR; ORAL

> DLT >		SARISOL		
> DLT >	AA	HALSEY	30MG/5ML	N84723 001
> ADD >		@	30MG/5ML	N84723 001

TABLET; ORAL

> DLT >		SARISOL NO. 1		
> DLT >	AA	HALSEY	15MG	N84719 001
> ADD >		@	15MG	N84719 001
> DLT >		SARISOL NO. 2		
> DLT >	AA	HALSEY	30MG	N84719 002
> ADD >		@	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

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

SOLUTION; INTRAPERITONEAL

	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
	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		
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

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

SOLUTION; INTRAPERITONEAL

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	
AB		25MG	N74433 002 FEB 13, 1996	
AB		50MG	N74433 003 FEB 13, 1996	
AB		100MG	N74433 004 FEB 13, 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	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	
AB		100MG	N74519 004 FEB 13, 1996	
AB	HALLMARK PHARMS	12.5MG	N74477 001 FEB 13, 1996	

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

AB	HALLMARK PHARMS	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	
AB		25MG	N74322 002 FEB 13, 1996	
AB		50MG	N74322 003 FEB 13, 1996	

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

AB	NOVOPHARM	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

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

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

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

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
ANCEF IN DEXTROSE 5% IN PLASTIC CONTAINER

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

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

> DLT > AB	HALSEY	5MG	N85340 001	
> DLT > AB		10MG	N85339 001	
> DLT > AB		25MG	N84685 001	
> ADD > @		5MG	N85340 001	
> ADD > @		10MG	N85339 001	
> ADD > @		25MG	N84685 001	

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

> DLT > AB	BARR	100MG	N88812 001	OCT 19, 1984
> DLT > AB		100MG	N89446 001	NOV 17, 1986
> DLT > AB		250MG	N88813 001	OCT 19, 1984

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

> DLT >	**AB**	BARR	**250MG**	**N89447 001**	
> DLT				NOV 17, 1986	
> ADD >		@	100MG	N88812 001	
> ADD >				OCT 19, 1984	
> ADD >		@	100MG	N89446 001	
> ADD >				NOV 17, 1986	
> ADD >		@	250MG	N88813 001	
> ADD >				OCT 19, 1984	
> ADD >		@	250MG	N89447 001	
> ADD >				NOV 17, 1986	
> DLT >	**AB**	HALSEY	**100MG**	**N89321 001**	
> DLT >				JAN 16, 1986	
> DLT >	**AB**		**250MG**	**N88662 001**	
> DLT >				JAN 09, 1986	
> ADD >		@	100MG	N89321 001	
> ADD >				JAN 16, 1986	
> ADD >		@	250MG	N88662 001	
> ADD >				JAN 09, 1986	
> DLT >	**AB**	SUPERPHARM	**250MG**	**N88695 001**	
> DLT >				SEP 17, 1984	
> ADD >		@	250MG	N88695 001	
> ADD >				SEP 17, 1984	

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

> DLT >	**AB**	SUPERPHARM	**50MG**	**N87247 001**	
> DLT >				FEB 09, 1983	
> ADD >		@	50MG	N87247 001	
> ADD >				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

> DLT >	**AB**	+ BRISTOL MYERS	**EQ 4GM RESIN/PACKET**	**N19669 001**	
> DLT >				DEC 05, 1988	

CHOLESTYRAMINE

POWDER; ORAL

QUESTRAN LIGHT

> ADD >	**AB**	BRISTOL MYERS	**EQ 4GM RESIN/PACKET**	**N19669 001**	
> ADD				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	
		+	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	

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL

CLOBETASOL PROPIONATE

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

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL

		ANAFRANIL			
> ADD >	**AB**	CIBA GEIGY	**25MG**	**N19906 001** DEC 29, 1989	
> ADD >					
> ADD >	**AB**	+	**50MG**	**N19906 002** DEC 29, 1989	
> ADD >					
> ADD >	**AB**		**75MG**	**N19906 003** DEC 29, 1989	
> ADD >					
> ADD >		**CLOMIPRAMINE HCL**			
> ADD >	**AB**	GENEVA PHARMS	**25MG**	**N74364 001** MAR 29, 1996	
> ADD >					
> ADD >	**AB**		**50MG**	**N74364 002** MAR 29, 1996	
> ADD >					
> ADD >	**AB**		**75MG**	**N74364 003** MAR 29, 1996	
> ADD >					

CROMOLYN SODIUM

CONCENTRATE; ORAL

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

DALTEPARIN SODIUM

INJECTABLE; INJECTION

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

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

	DESIPRAMINE HCL			
AB	EON LABS	**10MG**	**N74430 001** FEB 09, 1996	
AB		**150MG**	**N74430 002** FEB 09, 1996	

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

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

SUSPENSION/DROPS; OPHTHALMIC

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

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

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

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

TABLET, EXTENDED RELEASE; ORAL

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

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLOMINE HCL

> ADD >	**AB**	LANNETT	**10MG**	**N84285 001**	

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

> DLT >	**AA**	HALSEY	**50MG**	**N87914 001**	JUN 04, 1984
> DLT >					
> ADD >		@	50MG	N87914 001	JUN 04, 1984
> ADD >					

ELIXIR; ORAL

BELIX

> DLT >	**AA**	HALSEY	**12.5MG/5ML**	**N86586 001**	OCT 03, 1983
> DLT >					
> ADD >		@	12.5MG/5ML	N86586 001	OCT 03, 1983
> ADD >					

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

NORPACE CR

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

DOXYCYCLINE HYCLATE

TABLET; ORAL

DOXYCYCLINE HYCLATE

> DLT >	**AB**	SUPERPHARM	**EQ 100MG BASE**	**N62494 001**	FEB 20, 1985
> DLT >					
> ADD >		@	EQ 100MG BASE	N62494 001	FEB 20, 1985
> ADD >					

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

> ADD >		**EDROPHONIUM CHLORIDE**			
> ADD >	**AP**	STERIS	**10MG/ML**	**N40044 001**	MAR 20, 1996
> ADD >					
> ADD >		**EDROPHONIUM CHLORIDE PRESERVATIVE FREE**			
> ADD >	**AP**	STERIS	**10MG/ML**	**N40043 001**	MAR 20, 1996
> ADD >					
> ADD >		**TENSILON PRESERVATIVE FREE**			
> ADD >	**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

TABLET; ORAL

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

ESTRONE

INJECTABLE; INJECTION

		ESTROGENIC SUBSTANCE			
BP	+	**WYETH AYERST**	**2MG/ML**	**N83488 001**	
	@		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			
> ADD >	**AP**	LEDERLE LABS	**20MG/ML**	**N74513 001**	
> ADD >				MAR 14, 1996	
	AP	PHARMACHEMIE (NL)	**20MG/ML**	**N74227 001**	
				FEB 22, 1996	

EVANS BLUE

INJECTABLE; INJECTION

	EVANS BLUE			
	@ PARKE DAVIS	0.5%	N08041 001	

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			
> DLT >	**AB**	**SUPERPHARM**	**15MG**	**N71659 001**	
> DLT >				AUG 04, 1988	
> DLT >	**AB**		**30MG**	**N71660 001**	
> DLT >				AUG 04, 1988	
> ADD >		@	15MG	N71659 001	
> ADD >				AUG 04, 1988	
> ADD >		@	30MG	N71660 001	
> ADD >				AUG 04, 1988	

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION

> ADD >	FLOVENT			
> ADD >	GLAXO WELLCOME	0.044MG/INH		N20548 001
> ADD >				MAR 27, 1996
> ADD >		0.11MG/INH		N20548 002
> ADD >				MAR 27, 1996
> ADD >	+	0.22MG/INH		N20548 003
> ADD >				MAR 27, 1996

FOLIC ACID

TABLET; ORAL

		FOLIC ACID			
> DLT >	**AA**	**HALSEY**	**1MG**	**N83598 001**	
> ADD >		@	1MG	N83598 001	

FUROSEMIDE

TABLET; ORAL
FUROSEMIDE

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

GANCICLOVIR

IMPLANT; IMPLANTATION
VITRASERT

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

GENTAMICIN SULFATE

OINTMENT; OPHTHALMIC
GENTACIDIN

> ADD >	**AT**	CIBA	**EQ 0.3% BASE**	**N62501 001**
> ADD >				JUL 26, 1984
> DLT >	**AT**	IOLAB	**EQ 0.3% BASE**	**N62501 001**
> DLT >				JUL 26, 1984

SOLUTION/DROPS; OPHTHALMIC
GENTACIDIN

> ADD >	**AT**	CIBA	**EQ 0.3% BASE**	**N62480 001**
> ADD >				MAR 30, 1984
> DLT >	**AT**	IOLAB	**EQ 0.3% BASE**	**N62480 001**
> DLT >				MAR 30, 1984

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE

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

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

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

		HYDRALAZINE HCL		
> DLT >	**AA**	**HALSEY**	**10MG**	**N89218 001**
> DLT >				**JAN 22, 1986**
> ADD >		@	10MG	N89218 001
> ADD >				JAN 22, 1986

HYDROCHLOROTHIAZIDE

TABLET; ORAL

> DLT >		**HYDRO-D**		
> DLT >	**AB**	**HALSEY**	**25MG**	**N86504 001**
> DLT >	**AB**		**50MG**	**N83891 002**
> ADD >		@	25MG	N86504 001
> ADD >		@	50MG	N83891 002
		HYDROCHLOROTHIAZIDE		
> DLT >	**AB**	**BARR**	**50MG**	**N84771 001**
> ADD >		@	50MG	N84771 001
> DLT >	**AB**	**SUPERPHARM**	**25MG**	**N88827 001**
> DLT >				**DEC 28, 1984**
> DLT >	**AB**		**50MG**	**N88828 001**
> DLT >				**DEC 28, 1984**
> DLT >	**AB**		**100MG**	**N88829 001**
> DLT >				**DEC 28, 1984**
> ADD >		@	25MG	N88827 001
> ADD >				DEC 28, 1984
> ADD >		@	50MG	N88828 001
> ADD >				DEC 28, 1984
> ADD >		@	100MG	N88829 001
> ADD >				DEC 28, 1984

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

		METHYLDOPA AND HYDROCHLOROTHIAZIDE		
	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

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

	METHYLDOPA AND HYDROCHLOROTHIAZIDE		
	@ PARKE DAVIS	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	**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**
AT		**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

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

IBUPROFEN

TABLET; ORAL
IBUPROFEN

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

IBUPROFEN

TABLET; ORAL
IBUPROFEN

> ADD >		@ HALSEY	800MG	N72137 001
> ADD >				FEB 05, 1988

INDAPAMIDE

TABLET; ORAL
INDAPAMIDE

> ADD >	**AB**	MYLAN	**2.5MG**	**N74461 001**
> ADD >				MAR 27, 1996

INDINAVIR SULFATE

CAPSULE; ORAL
CRIXIVAN

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

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

> DLT >	**AB**	HALSEY	**25MG**	**N70782 001**
> DLT >				JUN 03, 1987
> DLT >	**AB**		**50MG**	**N70635 001**
> DLT >				JUN 03, 1987
> ADD >		@	25MG	N70782 001
> ADD >				JUN 03, 1987
> ADD >		@	50MG	N70635 001
> ADD >				JUN 03, 1987

IODIXANOL

INJECTABLE; INJECTION
VISIPAQUE 270

> ADD >	+ NYCOMED	55%	N20351 001
> ADD >			MAR 22, 1996

VISIPAQUE 320

> ADD >	+ NYCOMED	65.2%	N20351 002
> ADD >			MAR 22, 1996

IOPAMIDOL

>_ADD_>		INJECTABLE; INJECTION			
>_ADD_>		ISOVUE-200			
>_ADD_>		@ BRACCO	41%	N20327 001	
>_ADD_>				OCT 12, 1994	
>_ADD_>		ISOVUE-250			
>_ADD_>		BRACCO	51%	N20327 002	
>_ADD_>				OCT 12, 1994	
>_ADD_>		ISOVUE-300			
>_ADD_>		BRACCO	61%	N20327 003	
>_ADD_>				OCT 12, 1994	
>_ADD_>		ISOVUE-370			
>_ADD_>		BRACCO	76%	N20327 004	
>_ADD_>				OCT 12, 1994	
>_DLT_>		INJECTABLE; INTRAVASCULAR			
>_DLT_>		ISOVUE-200			
>_DLT_>		@ BRACCO	41%	N20327 001	
>_DLT_>				OCT 12, 1994	
>_DLT_>		ISOVUE-250			
>_DLT_>		BRACCO	51%	N20327 002	
>_DLT_>				OCT 12, 1994	
>_DLT_>		ISOVUE-300			
>_DLT_>		BRACCO	61%	N20327 003	
>_DLT_>				OCT 12, 1994	
>_DLT_>		ISOVUE-370			
>_DLT_>		BRACCO	76%	N20327 004	
>_DLT_>				OCT 12, 1994	

IRON DEXTRAN

	INJECTABLE; INJECTION			
	DEXFERRUM			
BP	LUITPOLD	EQ 50MG IRON/ML	N40024 001	
			FEB 23, 1996	

ISOSORBIDE MONONITRATE

	TABLET, EXTENDED RELEASE; ORAL				
	IMDUR				
>_DLT_>	@ SCHERING	30MG	N20225 001		
>_DLT_>			AUG 12, 1993		
>_ADD_>	+	30MG	N20225 001		
>_ADD_>			AUG 12, 1993		

KETAMINE HYDROCHLORIDE

		INJECTABLE; INJECTION			
		KETALAR			
>_ADD_>	**AP** +	PARKE DAVIS	**EQ 50MG BASE/ML**	**N16812 002**	
>_ADD_>	**AP** +		**EQ 100MG BASE/ML**	**N16812 003**	
>_ADD_>		**KETAMINE HCL**			
>_ADD_>	**AP**	BEDFORD	**EQ 50MG BASE/ML**	**N74524 001**	
>_ADD_>				MAR 22, 1996	
>_ADD_>	**AP**		**EQ 100MG BASE/ML**	**N74524 002**	
>_ADD_>				MAR 22, 1996	

LIDOCAINE HYDROCHLORIDE

		INJECTABLE; INJECTION			
		LIDOCAINE HCL			
	AP	ABBOTT	**20%**	**N89362 001**	
				MAY 25, 1988	
		@	20%	N89362 001	
				MAY 25, 1988	
		SOLUTION; ORAL			
		LIDOCAINE HCL			
>_ADD_>	**AT**	MORTON GROVE	**2%**	**N87872 001**	
>_ADD_>				NOV 18, 1982	
		LIDOCAINE HCL VISCOUS			
	AT	INTL MEDICATION	**2%**	**N86389 001**	
				FEB 02, 1982	
		@	2%	N86389 001	
				FEB 02, 1982	
>_DLT_>		**MYLOCAINE**			
>_DLT_>	**AT**	MORTON GROVE	**2%**	**N87872 001**	
>_DLT_>				NOV 18, 1982	
		SOLUTION; TOPICAL			
		ANESTACON			
>_DLT_>	**AT** +	ALCON	**2%**	**N80429 001**	
>_ADD_>	**AT** +	POLYMEDICA	**2%**	**N80429 001**	
		LIDOCAINE HCL			
>_ADD_>	**AT**	MORTON GROVE	**4%**	**N87881 001**	
>_ADD_>				NOV 18, 1982	
>_DLT_>		**MYLOCAINE**			
>_DLT_>	**AT**	MORTON GROVE	**4%**	**N87881 001**	
>_DLT_>				NOV 18, 1982	

LINDANE

CREAM; TOPICAL

> DLT >		+ KWELL	REED AND CARNRICK	1%	N06309 001
> DLT >				1%	N84218 001
> ADD >		@		1%	N06309 001
> ADD >		+		1%	N84218 001

LOTION; TOPICAL

> DLT >	AT	+ KWELL	REED AND CARNRICK	1%	N06309 003
> DLT >	AT			1%	N84218 002
> ADD >	AT	+		1%	N84218 002
> ADD >		@		1%	N06309 003

SHAMPOO; TOPICAL

> DLT >	AT	+ KWELL	REED AND CARNRICK	1%	N10718 001
> DLT >	AT			1%	N84219 001
> ADD >	AT	+		1%	N84219 001
> ADD >		@		1%	N10718 001

LORAZEPAM

TABLET; ORAL

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

LORAZEPAM

TABLET; ORAL

> ADD >		LORAZEPAM	@ SUPERPHARM	1MG	N71246 001 FEB 09, 1987
> ADD >		@		2MG	N71247 001 FEB 09, 1987

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

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

MEPROBAMATE

TABLET; ORAL

> DLT >	AA	MEPROBAMATE	BARR	600MG	N84230 001
> ADD >		@		600MG	N84230 001

METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL

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

METHYLDOPA

TABLET; ORAL
METHYLDOPA

>_DLT_>	**AB**	HALSEY	**500MG**	**N71753 001**	
>_DLT_>				**MAR 28, 1988**	
>_ADD_>		@	500MG	N71753 001	
>_ADD_>				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	

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

>_DLT_>	**AB**	HALSEY	**EQ 10MG BASE**	**N70906 001**	
>_DLT_>				**OCT 28, 1986**	
>_ADD_>		@	EQ 10MG BASE	N70906 001	
>_ADD_>				OCT 28, 1986	
	AB	SCHERING	**EQ 10MG BASE**	**N70598 001**	
				FEB 02, 1987	
		@	EQ 10MG BASE	N70598 001	
				FEB 02, 1987	
>_DLT_>	**AB**	SUPERPHARM	**EQ 10MG BASE**	**N70926 001**	
>_DLT_>				**JUN 26, 1987**	
>_ADD_>		@	EQ 10MG BASE	N70926 001	
>_ADD_>				JUN 26, 1987	

METRONIDAZOLE

TABLET; ORAL
METRONIDAZOLE

>_DLT_>	**AB**	HALSEY	**250MG**	**N70021 001**	
>_DLT_>				**APR 02, 1985**	
>_DLT_>	**AB**		**500MG**	**N70593 001**	
>_DLT_>				**FEB 27, 1986**	

METRONIDAZOLE

TABLET; ORAL
METRONIDAZOLE

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

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 SODIUM

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

NICOTINE

SPRAY, METERED; NASAL

NICOTROL

> ADD >	+	PHARMACIA	0.5MG/INH	N20385 001	
> ADD >				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	> ADD >
					> ADD >

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	

TRANSDERM-NITRO

BX		CIBA	0.1MG/HR	N20144 001	
				FEB 27, 1996	
BX			0.2MG/HR	N20144 002	
				FEB 27, 1996	
BX			0.4MG/HR	N20144 003	
				FEB 27, 1996	

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

TRANSDERM-NITRO

BX		CIBA	0.6MG/HR	N20144 004	
				FEB 27, 1996	
BX			0.8MG/HR	N20144 005	
				FEB 27, 1996	

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

MYCOLOG-II

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

OXYBUTYNIN CHLORIDE

SYRUP; ORAL

DITROPAN

AA	+	HOECHST MARION RSSL	5MG/5ML	N18211 001	> ADD >

OXYBUTYNIN CHLORIDE

AA		SILARX	5MG/5ML	N74520 001	> ADD >
				MAR 29, 1996	> ADD >

PENTAMIDINE ISETHIONATE

POWDER FOR RECONSTITUTION; INHALATION

NEBUPENT

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

PENTOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM PENTOBARBITAL

AA		HALSEY	100MG	N84677 001	> DLT >
	@		100MG	N84677 001	> ADD >

PERINDOPRIL ERBUMINE

TABLET; ORAL
ACEON

		AMARIC	2MG	N20184 001	DEC 30, 1993
			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

PREDNISOLONE ACETATE

> DLT >		SUSPENSION; OPHTHALMIC			
> DLT >		PRED FORTE			
> DLT >	BX	+ ALLERGAN	1%	N17011 001	
		SUSPENSION/DROPS; OPHTHALMIC			
> ADD >		PRED FORTE			
> ADD >	AB	+ ALLERGAN	1%	N17011 001	

PREDNISONE

TABLET; ORAL
PREDNISONE

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

> DLT >		WYETH AYERST	50MG	N10348 002
> DLT >		+	100MG	N10348 003
> ADD >		+	50MG	N10348 002
> ADD >		@	100MG	N10348 003

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPHENE 65

> DLT >		PROPHENE 65		
> DLT >	AA	HALSEY	65MG	N83538 002
> ADD >		@	65MG	N83538 002

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

> DLT >	BD	HALSEY	50MG	N80015 001
> ADD >		@	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			
>DLT>	**AB**	HALSEY	**324MG**	**N89476 001**	
>DLT>				**APR 10, 1987**	
>ADD>		@	324MG	N89476 001	
>ADD>				APR 10, 1987	

QUINIDINE SULFATE

CAPSULE; ORAL

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

TABLET; ORAL

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

RAMIPRIL

CAPSULE; ORAL

		ALTACE			
		HOECHST MARION RSSL	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	

>ADD> RITONAVIR

CAPSULE; ORAL

>ADD>		NORVIR			
>ADD>		+ ABBOTT	100MG	N20680 001	
>ADD>				MAR 01, 1996	

SOLUTION; ORAL

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

SERTRALINE HYDROCHLORIDE

TABLET; ORAL

		ZOLOFT			
>ADD>		PFIZER	EQ 25MG BASE	N19839 005	
>ADD>				MAR 06, 1996	

SUCRALFATE

TABLET; ORAL

		CARAFATE			
>ADD>	**AB**	+ BLUE RIDGE	**1GM**	**N18333 001**	
>ADD>		**SUCRALFATE**			
>ADD>	**AB**	BIOCRAFT	**1GM**	**N70848 001**	
>ADD>				MAR 29, 1996	

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

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

TAMOXIFEN CITRATE

TABLET; ORAL

	NOLVADEX			
>_DLT_>	@ ZENECA	EQ 20MG BASE	N17970 002	
>_DLT_>			**MAR 21, 1994**	
>_ADD_>	+	EQ 20MG BASE	N17970 002	
>_ADD_>			MAR 21, 1994	

TECHNETIUM TC-99M TETROFOSMIN KIT

INJECTABLE; INJECTION

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

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

		TETRACYCLINE HCL			
>_DLT_>	**AB**	SUPERPHARM	**250MG**	**N62540 001**	
>_DLT_>				**MAR 21, 1985**	
>_DLT_>	**AB**		**500MG**	**N62540 002**	
>_DLT_>				**MAR 21, 1985**	
>_ADD_>		@	250MG	N62540 001	
>_ADD_>				MAR 21, 1985	
>_ADD_>		@	500MG	N62540 002	
>_ADD_>				MAR 21, 1985	

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION

THALLOUS CHLORIDE TL 201				
>_DLT_>	MEDI PHYSICS	2mCi/ML	N18110 001	
>_DLT_>			**FEB 01, 1982**	
>_ADD_>		1mCi/ML	N18110 002	
>_ADD_>			FEB 27, 1996	

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

		THEOVENT			
>_DLT_>	**BC**	SCHERING	125MG	N87010 001	
>_DLT_>				JAN 31, 1985	
>_DLT_>	**BC**		250MG	N87910 001	
>_DLT_>				JAN 31, 1985	
>_ADD_>		@	125MG	N87010 001	
>_ADD_>				JAN 31, 1985	
>_ADD_>		@	250MG	N87910 001	
>_ADD_>				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	

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

		THIORIDAZINE HCL			
>_DLT_>	**AB**	SUPERPHARM	**10MG**	**N89103 001**	
>_DLT_>				**JUL 02, 1985**	
>_DLT_>	**AB**		**25MG**	**N89104 001**	
>_DLT_>				**JUL 02, 1985**	

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

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

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC
AKTOB

AT		AKORN	0.3%	N64096 001
				JAN 31, 1996

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

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

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

> DLT >	AB	ZENITH LABS	500MG	N18894 003
> DLT				NOV 02, 1984

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

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

TOLMETIN SODIUM

TABLET; ORAL
TOLMETIN SODIUM

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

VERAPAMIL HYDROCHLORIDE

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

> ADD > BROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

> ADD > TABLET, EXTENDED RELEASE; ORAL
> ADD > EFIDAC 24 PSEUDOEPHEDRINE HCL/BROMPHENIRAMINE MALEATE
> ADD > + ALZA 16MG;240MG N19672 001
> ADD > 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
> DLT > HALSEY 200MG N71027 001
> DLT > SEP 29, 1987
> ADD > @ 200MG N71027 001
> ADD > SEP 29, 1987

IBUPROFEN

TABLET; ORAL
IBUPROFEN
@ LEMMON 200MG N73141 001
MAY 29, 1992
TAG PHARMS 200MG N73141 001
MAY 29, 1992

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
\+ NOVO NORDISK 100 UNITS/ML N18385 001
@ 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

MICONAZOLE NITRATE

CREAM; VAGINAL

>ADD>	MICONAZOLE 7			
>ADD>	NMC	2%	N74164 001	MAR 29, 1996
>ADD>				
	MICONAZOLE NITRATE			
	G AND W LABS	2%	N74366 001	FEB 22, 1996

MINOXIDIL

SOLUTION; TOPICAL

	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

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

>ADD>	EFIDAC 24 PSEUDOEPHEDRINE HCL			
>ADD>	+ CIBA	240MG	N20021 002	DEC 15, 1992
>ADD>				
>DLT>	EFIDAC/24			
>DLT>	+ CIBA	240MG	N20021 002	DEC 15, 1992
>DLT>				

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 3 / MAR '96

NO MARCH 1996 APPROVALS

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January 1, 1996 thru March 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 racemose (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= / /
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= / /
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= / /
Interferon beta-1a TN=Rebif	Treatment of patients with secondary progressive multiple sclerosis.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/11/96 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= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
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= / /

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
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

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

NO MARCH 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.

NO MARCH 1996 ADDITIONS

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS

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.

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

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
ATRACURIUM BESYLATE INJECTABLE; INJECTION	0.5MG/ML 1MG/ML (100ML CONTAINER)	95 P-0372/ CP1	ABBOTT	NEW STRENGTH	APPROVED MAR 08, 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
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

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

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

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

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		
	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
	20421 001	BUTOCONAZOLE NITRATE; FEMSTAT 3	4078071	JUL 28, 1997			
						NP	DEC 21, 1998
	20313 002	CALCITONIN, SALMON; MIACALCIN	4344949	OCT 03, 2000			
>ADD>	18874 001	CALCITRIOL; CALCIJEX	4308264	JAN 28, 2001			
>ADD>	18874 002	CALCITRIOL; CALCIJEX	4308264	JAN 28, 2001			
	18343 004	CAPTOPRIL; CAPOTEN				I-95	SEP 23, 1996
						I-101	JAN 28, 1997
	18343 007	CAPTOPRIL; CAPOTEN				I-95	SEP 23, 1996
						I-101	JAN 28, 1997
>ADD>	20234 001	CARBAMAZEPINE; TEGRETOL-XR	5284662	FEB 08, 2011			
>ADD>			RE34990	JUL 29, 2007			
>ADD>	20234 002	CARBAMAZEPINE; TEGRETOL-XR	5284662	FEB 08, 2011			
>ADD>			RE34990	JUL 29, 2007			
>ADD>	20234 003	CARBAMAZEPINE; TEGRETOL-XR	5284662	FEB 08, 2011			
>ADD>			RE34990	JUL 29, 2007			
	19835 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
	19835 002	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
	20398 001	CISAPRIDE MONOHYDRATE; PROPULSID	4962115	OCT 09, 2007	U-79	NCE	JUL 29, 1998
	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		
	20479 001	CROMOLYN SODIUM; GASTROCROM	4515805	MAY 07, 2002	U-130		
			4421762	DEC 20, 2000	U-130		
>ADD>	20287 003	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2000		NCE	DEC 22, 1999
	20118 001	DESFLURANE; SUPRANE	4762856	FEB 02, 2007	U-67	NCE	SEP 18, 1997
>ADD>	19955 001	DESMOPRESSIN ACETATE; DDAVP	5047398	SEP 10, 2008			
>ADD>	19955 002	DESMOPRESSIN ACETATE; DDAVP	5047398	SEP 10, 2008			
>ADD>	20254 001	DICLOFENAC SODIUM; VOLTAREN-XR				NDF	MAR 08, 1999
>ADD>	18723 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
>ADD>	18723 002	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
>ADD>	18723 003	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 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>	20164 001	ENOXAPARIN SODIUM; LOVENOX	5389618	FEB 14, 2012			
			4692435	DEC 24, 2004	U-123		
			4486420	DEC 04, 2001	U-122		
	20195 007	FENTANYL CITRATE; FENTANYL	4671953	JUN 09, 2004	U-87	NDF	OCT 04, 1996
>ADD>	20548 001	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
>ADD>	20548 002	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
>ADD>	20548 003	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
	20235 001	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
	20235 002	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
	20235 003	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
	20123 001	GADODIAMIDE; OMNISCAN	4687659	MAY 04, 2007		D-29	FEB 05, 1999
						I-145	FEB 05, 1999
						I-144	FEB 05, 1999
	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4647447	MAR 03, 2004		I-146	FEB 28, 1999
>ADD>	20569 001	GANCICLOVIR; VITRASERT				NP	MAR 04, 1996
>ADD>						ODE	MAR 04, 2003
>ADD>	20578 001	GOSERELIN ACETATE; ZOLADEX	5366734	NOV 22, 2011			
>ADD>			4767628	AUG 30, 2005			
>ADD>			4100274	APR 22, 1999		NP	JAN 11, 1999
	20239 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-89		
	20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-105		
>ADD>	20685 001	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
>ADD>	20685 003	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
>ADD>	20351 001	IODIXANOL; VISIPAQUE 270	5349085	SEP 20, 2011		NCE	MAR 22, 2001
>ADD>			4396597	JUL 03, 1999			
>ADD>			4278654	JUL 03, 1999			
>ADD>	20351 002	IODIXANOL; VISIPAQUE 320	5349085	SEP 20, 2011		NCE	MAR 22, 2001
>ADD>			4396597	JUL 03, 1999			
>ADD>			4278654	JUL 03, 1999			
	20564 001	LAMIVUDINE; EPIVIR	5047407	FEB 08, 2009			
	20596 001	LAMIVUDINE; EPIVIR	5047407	FEB 08, 2009			
	20406 001	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126		
	20406 002	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126		

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
	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>	20312 001	MOEXIPRIL HYDROCHLORIDE; UNIVASC	4344949	OCT 03, 2000			
>ADD>	20312 002	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
>ADD>	19810 001	OMEPRAZOLE; PRILOSEC	4255431	APR 05, 2001	U-108	I-23	MAR 22, 1999
>ADD>	19810 003	OMEPRAZOLE; PRILOSEC	4853230	APR 20, 2007	U-108	I-23	MAR 22, 1999
>ADD>	19887 002	PENTAMIDINE ISETHIONATE; NEBUPENT				I-148	MAR 05, 1999
	20184 001	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	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
>ADD>	19898 006	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008			
>ADD>			5030447	JUL 09, 2008			
>ADD>			4346227	OCT 20, 2005			
>ADD>	19898 007	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008			
>ADD>			5030447	JUL 09, 2008			
>ADD>			4346227	OCT 20, 2005			
	20545 001	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 1999
	20545 002	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 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
	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		
>ADD>	20659 001	RITONAVIR; NORVIR	5484801	JAN 28, 2014		NCE	MAR 01, 2001
>ADD>	20680 001	RITONAVIR; NORVIR				NCE	MAR 01, 2001
	20628 001	SAQUINAVIR MESYLATE; INVIRASE	5196438	NOV 19, 2010			
>ADD>	19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL	5242950	APR 23, 2012		ODE	JUN 05, 1996
>ADD>			5151419	SEP 29, 2009			
>ADD>			4880833	NOV 14, 2006			
	20280 004	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998
	20280 006	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998
	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		
	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

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>	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
>DLT>	~~19057 001~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~4112097~~	~~JAN 21, 1997*~~			
>ADD>	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
>DLT>	~~19057 002~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~4112097~~	~~JAN 21, 1997*~~			
>ADD>	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
>DLT>	~~19057 003~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~4112097~~	~~JAN 21, 1997*~~			
>ADD>	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
>DLT>	~~19057 004~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~4112097~~	~~JAN 21, 1997*~~			
>ADD>	20347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
>DLT>	~~20347 001~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~4112097~~	~~JAN 21, 1997*~~			
>ADD>	20347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
>DLT>	~~20347 002~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~4112097~~	~~JAN 21, 1997*~~			
>ADD>	20347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
>DLT>	~~20347 003~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~4112097~~	~~JAN 21, 1997*~~			
>ADD>	20347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
>DLT>	~~20347 004~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~4112097~~	~~JAN 21, 1997*~~			
	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>	19963 001	TRETINOIN; RENOVA	4877805	OCT 31, 2006	U-131		
>ADD>			4603146	JUL 29, 2003	U-131		
>ADD>			4423041	DEC 27, 2000			
>ADD>	19594 002	URSODIOL; ACTIGALL				I-147	MAR 29, 1999
	20487 001	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 1998
	20487 002	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 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

*SEE SECTION 1.4 OF INTRODUCTION

*U.S. Government Printing Office: 1996 - 404-907/20010

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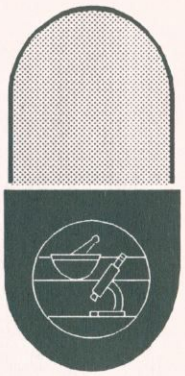

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