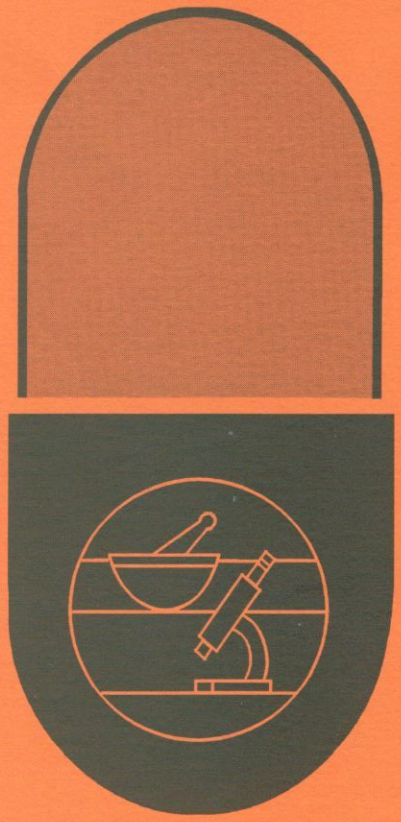
CUMULATIVE SUPPLEMENT 1 JAN'96



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

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

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with
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16TH EDITION

Cumulative Supplement 1

JANUARY 1996

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

CUMULATIVE SUPPLEMENT 1
JANUARY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 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)

THERE WERE NO APPLICANT NAME CHANGES IN JANUARY 1996.

1.5 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.

1.6 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; CODEINE PHOSPHATE

TABLET; ORAL

> ADD > **ACETAMINOPHEN AND CODEINE PHOSPHATE**
> ADD > AA MIKART 300MG;60MG N89244 001
> ADD > FEB 25, 1986
> DLT > **ACETAMINOPHEN AND CODEINE PHOSPHATE #4**
> DLT > AA MIKART 300MG;60MG N89244 001
> DLT > FEB 25, 1986

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

> ADD > LORTAB
> ADD > UCB PHARMA 500MG;10MG N40100 001
> ADD > JAN 26, 1996

AMOXICILLIN

TABLET, CHEWABLE; ORAL

AMOXICILLIN

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

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

SOLUTION; INTRAPERITONEAL

> ADD > **DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER**
> ADD > AT FRESENIUS 25.7MG/100ML;1.5GM/100ML;
> ADD > 15.2MG/100ML;567MG/100ML;
> ADD > 392MG/100ML N18379 002
> ADD > **DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER**
> ADD > AT FRESENIUS 25.7MG/100ML;2.5GM/100ML;
> ADD > 15.2MG/100ML;567MG/100ML;
> ADD > 392MG/100ML N18379 003
> ADD > **DELFLEX W/ DEXTROSE 3.5% IN PLASTIC CONTAINER**
> ADD > AT FRESENIUS 25.7MG/100ML;3.5GM/100ML;
> ADD > 15.2MG/100ML;567MG/100ML;
> ADD > 392MG/100ML N18379 007
> ADD > JUN 24, 1988

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

SOLUTION; INTRAPERITONEAL

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

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

SOLUTION; INTRAPERITONEAL

>_DLT_>		**INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER**			
>_DLT_>	AT	FRESENIUS	25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML		N18379 004 JUL 07, 1982
>_DLT_>		**INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER**			
>_DLT_>	AT	FRESENIUS	25.7MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML		N18379 005 JUL 07, 1982
>_DLT_>		**INPERSOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER**			
>_DLT_>	AT	FRESENIUS	25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML		N18379 008 JUN 24, 1988
>_DLT_>		**INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER**			
>_DLT_>	AT	FRESENIUS	25.7MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML		N18379 006 JUL 07, 1982

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

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

>_ADD_> CEFEPIME HYDROCHLORIDE (ARGININE FORMULATION)

INJECTABLE; INJECTION

MAXIPIME

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

CHROMIC CHLORIDE

INJECTABLE; INJECTION

CHROMIC CHLORIDE

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

CHROMIC CHLORIDE IN PLASTIC CONTAINER

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

CIMETIDINE

TABLET; ORAL

CIMETIDINE

>_ADD_>	AB	INVAMED	200MG		N74506 001 JAN 24, 1996
>_ADD_>	AB		300MG		N74506 002 JAN 24, 1996
>_ADD_>	AB		400MG		N74506 003 JAN 24, 1996
>_ADD_>	AB		800MG		N74506 004 JAN 24, 1996

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DEXTROAMPHETAMINE SULFATE

>_DLT_>	AA	HALSEY	10MG		N83930 001
>_ADD_>		@	10MG		N83930 001
>_DLT_>	AA	MM MAST	5MG		N86521 001
>_ADD_>		@	5MG		N86521 001
>_DLT_>	AA	+ REXAR	10MG		N84051 002
>_ADD_>		+	10MG		N84051 002

ESTRONE

INJECTABLE; INJECTION

ESTROGENIC SUBSTANCE

>_DLT_>	BP	+ WYETH AYERST	2MG/ML		N83488 001
>_ADD_>		@	2MG/ML		N83488 001

NATURAL ESTROGENIC SUBSTANCE-ESTRONE

>_DLT_>	BP	STERIS	2MG/ML		N85237 001 NOV 23, 1982

ESTRONE

INJECTABLE; INJECTION
NATURAL ESTROGENIC SUBSTANCE-ESTRONE

> ADD >	+	STERIS	2MG/ML	N85237 001	
> ADD >				NOV 23, 1982	

GOSERELIN ACETATE

IMPLANT; IMPLANTATION
ZOLADEX

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

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

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

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

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALDOL DECANOATE 100

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

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

> ADD >	**AB**	SIDMAK LABS NJ	**50MG;75MG**	**N73467 001**	
> ADD >				JAN 31, 1996	

HYDROCORTISONE

OINTMENT; TOPICAL
PENECORT

> DLT >					
> DLT >	**AT**	ALLERGAN HERBERT	**2.5%**	**N88217 001**	
> DLT >				JUN 06, 1984	
> ADD >		@	2.5%	N88217 001	
> ADD >				JUN 06, 1984	

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL
HYDROXYCHLOROQUINE SULFATE

> ADD >	**AB**	INVAMED	**200MG**	**N40150 001**	
> ADD >				JAN 27, 1996	

LIDOCAINE HYDROCHLORIDE

SOLUTION; ORAL
LIDOCAINE HCL VISCOUS

> DLT >	**AT**	INTL MEDICATION	**2%**	**N86389 001**	
> DLT >				FEB 02, 1982	
> ADD >		@	2%	N86389 001	
> ADD >				FEB 02, 1982	

MANGANESE SULFATE

INJECTABLE; INJECTION
MANGANESE SULFATE

> DLT >		FUJISAWA	EQ 0.1MG MANGANESE/ML	N19228 001	
> DLT >				MAY 05, 1987	
> ADD >		@	EQ 0.1MG MANGANESE/ML	N19228 001	
> ADD >				MAY 05, 1987	

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

> DLT >	**AB**	SCHERING	**EQ 10MG BASE**	**N70598 001**	
> DLT >				FEB 02, 1987	
> ADD >		@	EQ 10MG BASE	N70598 001	
> ADD >				FEB 02, 1987	

NADOLOL

TABLET; ORAL
NADOLOL

> ADD >	**AB**	ZENITH LABS	**80MG**	**N74255 001**	
> ADD >				JAN 24, 1996	
> ADD >	**AB**		**120MG**	**N74255 002**	
> ADD >				JAN 24, 1996	
> ADD >	**AB**		**160MG**	**N74255 003**	
> ADD >				JAN 24, 1996	

NAPROXEN SODIUM

>ADD<		TABLET, EXTENDED RELEASE; ORAL			
>ADD<		NAPRELAN			
>ADD<	+	ELAN PHARM	EQ 375MG BASE	N20353 001	
>ADD<				JAN 05, 1996	
>ADD<	+		EQ 500MG BASE	N20353 002	
>ADD<				JAN 05, 1996	
>ADD<	+		EQ 750MG BASE	N20353 003	
>ADD<				JAN 05, 1996	

PERINDOPRIL ERBUMINE

		TABLET; ORAL			
		ACEON			
>DLT<		AMARIC	2MG	N20184 001	
>DLT<				DEC 30, 1993	
>DLT<			4MG	N20184 002	
>DLT<				DEC 30, 1993	
>DLT<	+		8MG	N20184 003	
>DLT<				DEC 30, 1993	
>ADD<		RHONE POULENC RORER	2MG	N20184 001	
>ADD<				DEC 30, 1993	
>ADD<			4MG	N20184 002	
>ADD<				DEC 30, 1993	
>ADD<	+		8MG	N20184 003	
>ADD<				DEC 30, 1993	

PROCAINAMIDE HYDROCHLORIDE

		TABLET, EXTENDED RELEASE; ORAL			
>ADD<		PROCANBID			
>ADD<	+	PARKE DAVIS	500MG	N20545 001	
>ADD<				JAN 31, 1996	
>ADD<	+		1GM	N20545 002	
>ADD<				JAN 31, 1996	

PROTIRELIN

		INJECTABLE; INJECTION			
>DLT<		THYPINONE			
>DLT<	AP	+ ABBOTT	0.5MG/ML	N17638 001	
>ADD<		@	0.5MG/ML	N17638 001	
		THYREL TRH			
>DLT<	AP	FERRING LABS	0.5MG/ML	N18087 001	
>ADD<	+		0.5MG/ML	N18087 001	

RAMIPRIL

		CAPSULE; ORAL			
		ALTACE			
>ADD<		HOECHST MARION RSSL	1.25MG	N19901 001	
>ADD<				JAN 28, 1991	
>ADD<			2.5MG	N19901 002	
>ADD<				JAN 28, 1991	
>ADD<			5MG	N19901 003	
>ADD<				JAN 28, 1991	
>ADD<	+		10MG	N19901 004	
>ADD<				JAN 28, 1991	
>DLT<		HOECHST ROUSSEL	1.25MG	N19901 001	
>DLT<				JAN 28, 1991	
>DLT<			2.5MG	N19901 002	
>DLT<				JAN 28, 1991	
>DLT<			5MG	N19901 003	
>DLT<				JAN 28, 1991	
>DLT<	+		10MG	N19901 004	
>DLT<				JAN 28, 1991	

THEOPHYLLINE

		INJECTABLE; INJECTION			
		THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER			
>DLT<	AP	MCGAW	40MG/100ML	N19083 001	
>DLT<				NOV 07, 1984	
>ADD<		@	40MG/100ML	N19083 001	
>ADD<				NOV 07, 1984	
		THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER			
>DLT<	AP	MCGAW	80MG/100ML	N19083 002	
>DLT<				NOV 07, 1984	
>ADD<		@	80MG/100ML	N19083 002	
>ADD<				NOV 07, 1984	
		THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER			
>DLT<	AP	MCGAW	160MG/100ML	N19083 003	
>DLT<				NOV 07, 1984	
>ADD<		@	160MG/100ML	N19083 003	
>ADD<				NOV 07, 1984	

TOBRAMYCIN

		SOLUTION/DROPS; OPHTHALMIC			
>ADD<		AKTOB			
>ADD<	AT	AKORN	0.3%	N64096 001	
>ADD<				JAN 31, 1996	

TRETINOIN

CREAM; TOPICAL

> ADD >	RENOVA			
> ADD >	JOHNSON RW	0.05%	N19963 001	
> ADD >			DEC 29, 1995	

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

>ADD>	OCUHIST			
>ADD>	AKORN	0.025%;0.3%	N20485 001	
>ADD>			JAN 31, 1996	

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 1 / JAN '96

NO JANUARY 1996 APPROVALS

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January, 1996]

NAME
Generic/Chemical
TN=Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS
DD=Date Designated
MA=Marketing Approval

Albendazole
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
1996-01-17

Albendazole
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
1996-01-18

Antihemophilic factor (human)
Alphanate
Treatment of von Willebrand's disease.
Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles, CA 90032
1996-01-05

Nitazoxanide
Treatment of cryptosporidiosis in HIV-positive and AIDS patients.
Unimed Pharmaceuticals, Inc.
2150 East Lake Cook Road, Suite 210
Buffalo Grove, IL 60089
1996-01-05

Valine, isoleucine and leucine
VIL
Treatment of hyperphenylalaninemia.
Leas Research Products
4 Brookview Lane
Troy, NY 12180
1996-01-05

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

NO JANUARY 1996 ORPHAN DRUG PRODUCT APPROVALS

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

NO JANUARY 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 JANUARY 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.

NO ANDA SUITABILITY PETITIONS APPROVED OR DENIED IN JANUARY 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 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

PATENT USE CODE

U-127	METHOD OF PRODUCING NEUROMUSCULAR BLOCKADE

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>	19806 001	ACRIVASTINE; SEMPREX-D	4650807	MAR 26, 2008	U-93		
>DLT>	~~19806 001~~	~~ACRIVASTINE; SEMPREX-D~~	~~4650807~~	~~MAR 17, 2004~~	~~U-93~~		
>ADD>	20541 001	ANASTROZOLE; ARIMIDEX	4935437	JUN 10, 2008			
>ADD>	20428 001	AZELAIC ACID; AZELEX	4386104	MAY 31, 2000	U-124		
>ADD>	20498 001	BICALUTAMIDE; CASODEX	4636505	JAN 13, 2004			
>ADD>	20421 001	BUTOCONAZOLE NITRATE; FEMSTAT 3	4078071	JUL 28, 1997		NP	DEC 21, 1998
>ADD>	18343 004	CAPTOPRIL; CAPOTEN				I-95	SEP 23, 1996
>ADD>						I-101	JAN 28, 1997
>ADD>	18343 007	CAPTOPRIL; CAPOTEN				I-95	SEP 23, 1996
>ADD>						I-101	JAN 28, 1997
>ADD>	19835 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
>ADD>	19835 002	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
>ADD>	20551 001	CISATRACURIUM BESYLATE; NIMBEX	5453510	SEP 26, 2012	U-127		
>ADD>			4179507	DEC 18, 1996	U-127		
>ADD>	20551 002	CISATRACURIUM BESYLATE; NIMBEX PRESERVATIVE FREE	5453510	SEP 26, 2012	U-127		
>ADD>			4179507	DEC 18, 1996	U-127		
>ADD>	20551 003	CISATRACURIUM BESYLATE; NIMBEX PRESERVATIVE FREE	5453510	SEP 26, 2012	U-127		
>ADD>			4179507	DEC 18, 1996	U-127		
>ADD>	20164 001	ENOXAPARIN SODIUM; LOVENOX	4692435	DEC 24, 2004	U-123		
>ADD>			4486420	DEC 04, 2001	U-122		
>ADD>	20235 001	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
>ADD>			4894476	MAY 02, 2008			
>DLT>	~~20235 001~~	~~GABAPENTIN; NEURONTIN~~	~~4894476~~	~~JAN 16, 2007~~			
>ADD>	20235 002	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
>ADD>			4894476	MAY 02, 2008			
>DLT>	~~20235 002~~	~~GABAPENTIN; NEURONTIN~~	~~4894476~~	~~JAN 16, 2007~~			
>ADD>	20235 003	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
>ADD>			4894476	MAY 02, 2008			
>DLT>	~~20235 003~~	~~GABAPENTIN; NEURONTIN~~	~~4894476~~	~~JAN 16, 2007~~			
>ADD>	20123 001	GADODIAMIDE; OMNISCAN	4687659	MAY 04, 2007			
>ADD>	20578 001	GOSERELIN ACETATE; ZOLADEX				NP	JAN 11, 1999
>ADD>	20239 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-89		
>DLT>	~~20239 001~~	~~GRANISETRON HYDROCHLORIDE; KYTRIL~~	~~4886808~~	~~DEC 12, 2006~~	~~U-89~~		
>ADD>	20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-105		
>DLT>	~~20305 001~~	~~GRANISETRON HYDROCHLORIDE; KYTRIL~~	~~4886808~~	~~DEC 12, 2006~~	~~U-105~~		
>ADD>	20564 001	LAMIVUDINE; EPIVIR	5047407	FEB 08, 2009			
>ADD>	20596 001	LAMIVUDINE; EPIVIR	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>	20406 001	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126		
>ADD>	20406 002	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126		
>ADD>	19558 001	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
>ADD>	19558 002	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
>ADD>	19558 003	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
>ADD>	19558 004	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
>ADD>	19558 006	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
>ADD>	19777 001	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
>ADD>	19777 002	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
>ADD>	19777 003	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
>ADD>	19777 004	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
>ADD>	19777 005	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
>ADD>	19940 001	MASOPROCOL; ACTINEX	4695590	APR 17, 2008			
>ADD>	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	JUN 11, 2011			
>ADD>	20184 001	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
>DLT>	~~20184 001~~	~~PERINDOPRIL ERBUMINE; ACEON~~	~~4508729~~	~~APR 02, 2002~~			
>ADD>	20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
>DLT>	~~20184 002~~	~~PERINDOPRIL ERBUMINE; ACEON~~	~~4508729~~	~~APR 02, 2002~~			
>ADD>	20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
>DLT>	~~20184 003~~	~~PERINDOPRIL ERBUMINE; ACEON~~	~~4508729~~	~~APR 02, 2002~~			
>ADD>	20451 001	PORFIMER SODIUM; PHOTOFRIN				ODE	DEC 27, 2002
>ADD>	20545 001	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 1999
>ADD>	20545 002	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 1999
>ADD>	19885 001	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
>ADD>	19885 002	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
>ADD>	19885 003	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
>ADD>	19885 004	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
>ADD>	20520 001	RANITIDINE HYDROCHLORIDE; ZANTAC 75	4880636	MAY 13, 2008			
>ADD>			4521431	JUN 04, 2002	U-121		
>ADD>			4128658	JUL 25, 1997	U-121		

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>	20272 001	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
>DLT>	~~20272 001~~	~~RISPERIDONE; RISPERDAL~~	~~4804663~~	~~FEB 14, 2006~~	~~U-90~~		
>ADD>	20272 002	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
>DLT>	~~20272 002~~	~~RISPERIDONE; RISPERDAL~~	~~4804663~~	~~FEB 14, 2006~~	~~U-90~~		
>ADD>	20272 003	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
>DLT>	~~20272 003~~	~~RISPERIDONE; RISPERDAL~~	~~4804663~~	~~FEB 14, 2006~~	~~U-90~~		
>ADD>	20272 004	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
>DLT>	~~20272 004~~	~~RISPERIDONE; RISPERDAL~~	~~4804663~~	~~FEB 14, 2006~~	~~U-90~~		
>ADD>	20272 005	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
>DLT>	~~20272 005~~	~~RISPERIDONE; RISPERDAL~~	~~4804663~~	~~FEB 14, 2006~~	~~U-90~~		
>ADD>	20628 001	SAQUINAVIR MESYLATE; INVIRASE	5196438	NOV 19, 2010			
>ADD>	20412 001	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
>DLT>	~~20412 001~~	~~STAVUDINE; ZERIT~~	~~4978655~~	~~DEC 18, 2007~~	~~U-94~~		
>ADD>	20412 002	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
>DLT>	~~20412 002~~	~~STAVUDINE; ZERIT~~	~~4978655~~	~~DEC 18, 2007~~	~~U-94~~		
>ADD>	20412 003	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
>DLT>	~~20412 003~~	~~STAVUDINE; ZERIT~~	~~4978655~~	~~DEC 18, 2007~~	~~U-94~~		
>ADD>	20412 004	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
>DLT>	~~20412 004~~	~~STAVUDINE; ZERIT~~	~~4978655~~	~~DEC 18, 2007~~	~~U-94~~		
>ADD>	20412 005	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
>DLT>	~~20412 005~~	~~STAVUDINE; ZERIT~~	~~4978655~~	~~DEC 18, 2007~~	~~U-94~~		
>ADD>	19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE				I-142	DEC 14, 1998
>ADD>	20487 001	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 1998
>ADD>	20487 002	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 1998

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