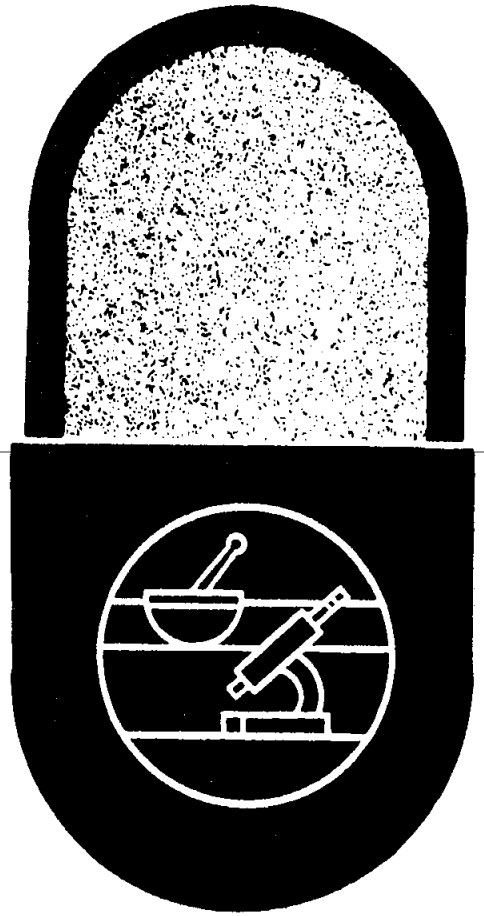
CUMULATIVE SUPPLEMENT 3
JAN'89-MAR'89



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH 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

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with

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CUMULATIVE SUPPLEMENT 3

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1.0 INTRODUCTIDN

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, 9th 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 in the Division of Blood and Blood Products approved under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 in the Division of Blood and Blood Products Approved Under Section 505 of the Act lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product, along with the application number and product number (FDA's internal file number). All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section 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 effective date for the approved drug product (the earliest date a product may be marketed) appears, when appropriate, to the left of the approval date.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Additions new to the Prescription Drug Product List, OTC Drug Product List, Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (✖) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the Prescription Drug Product List, OTC Orug Product List, Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print will remain in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data will be dropped in subsequent Cumulative Supplements.

Products discontinued from marketing or products which have had their approval withdrawn for other than safety or effectiveness reasons, will be flagged in this Cumulative Supplement with the " ∂ " symbol to designate their non-marketed status. All products having a " ∂ " symbol in the 12th Cumulative Supplement of the 9th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 9th 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 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Tranylcypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.3 APPLICANT (NAME) CHANGES

Because it is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	NEW ABBREVIATED NAME
SCHERING CORP SUB SCHERING PLOUGH CORP	SCHERING CORP	SCHERING

1.4 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 1988) 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.

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1988	MAR 1989	JUN 1989	SEP 1989
DRUG PRODUCTS LISTED	10091	10157		
SINGLE SOURCE	1983 (19.7%)	1993 (19.6%)		
MULTISOURCE	8108 (80.3%)	8164 (80.4%)		
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)	7321 (72.1%)		
NOT THERAPEUTICALLY EQUIVALENT	748 (7.4%)	726 (7.1%)		
EXCEPTIONS[1]	118 (1.1%)	117 (1.2%)		
NEW MOLECULAR ENTITIES APPROVED	--	3		
NUMBER OF APPLICANTS	374	393		

[1]Amino acid-containing products of varying composition (see Introduction, page I-7 of the List).

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE

/AA/	/PBI/	/300MG;30MG/	/N87919/001/	/JUN/22,/1982/
/AA/		/300MG;60MG/	/N87920/001/	/JUN/22,/1982/
	∂ PBI	300MG;30MG	N87919 001	JUN 22, 1982
	∂	300MG;60MG	N87920 001	JUN 22, 1982
>DLT >/AA/	/WHITE/TN/PAULSN/	/300MG;60MG/	/N85607/001/	
>ADD >	∂ WHITE TN PAULSN	300MG;60MG	N85607 001	

PAPA-DEINE #3

/AA/	/VANGARD/LABS/	/300MG;30MG/	/N88037/001/	/MAR/20,/1984/
	∂ VANGARD LABS	300MG;30MG	N88037 001	MAR 20, 1984

PAPA-DEINE #4

/AA/	/VANGARD/LABS/	/300MG;60MG/	/N88715/001/	/MAR/20,/1984/
	∂ VANGARD LABS	300MG;60MG	N88715 001	MAR 20, 1984

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

AA	LUCHEM PHARMS	500MG;5MG¤	N89907 001 JAN 13, 1989

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE 5/APAP 500

AA	DUPONT PHARMS	500MG;5MG	N85911 001

ROXICET 5/500

AA	ROXANE LABS	500MG;5MG¤	N89775 001 JAN 12, 1989

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

/AB/	/VANGARD/LABS/	/250MG/	/N87654/001/	/FEB/05,/1982/
	∂ VANGARD LABS	250MG	N87654 001	FEB 05, 1982

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	AM THERPTCS	EQ 2MG BASE¤	N72449 001	DEC 05, 1989 : FEB 01, 1989
AB		EQ 4MG BASE¤	N72450 001	DEC 05, 1989 : FEB 01, 1989
>ADD > AB	CORD LABS	EQ 2MG BASE¤	N72151 001	DEC 05, 1989 : MAR 23, 1989
>ADD > AB		EQ 4MG BASE¤	N72152 001	DEC 05, 1989 : MAR 23, 1989
AB	MUTUAL PHARM	EQ 2MG BASE¤	N72636 001	DEC 05, 1989 : FEB 01, 1989
AB		EQ 4MG BASE¤	N72637 001	DEC 05, 1989 : FEB 01, 1989
AB	SIDMAK LABS	EQ 2MG BASE¤	N72316 001	DEC 05, 1989 : JAN 30, 1989
AB		EQ 4MG BASE¤	N72317 001	DEC 05, 1989 : JAN 30, 1989

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

TRAVASOL 2.75% IN DEXTROSE 10% IN PLASTIC CONTAINER			
BAXTER	2.75%;10GM/100ML	N19520 002	SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 15% IN PLASTIC CONTAINER			
BAXTER	2.75%;15GM/100ML	N19520 003	SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 20% IN PLASTIC CONTAINER			
BAXTER	2.75%;20GM/100ML	N19520 004	SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 25% IN PLASTIC CONTAINER			
BAXTER	2.75%;25GM/100ML	N19520 005	SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 5% IN PLASTIC CONTAINER			
BAXTER	2.75%;5GM/100ML	N19520 001	SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 10% IN PLASTIC CONTAINER			
BAXTER	4.25%;10GM/100ML	N19520 007	SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 15% IN PLASTIC CONTAINER			
BAXTER	4.25%;15GM/100ML	N19520 008	SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 20% IN PLASTIC CONTAINER			
BAXTER	4.25%;20GM/100ML	N19520 009	SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 25% IN PLASTIC CONTAINER			
BAXTER	4.25%;25GM/100ML	N19520 010	SEP 23, 1988

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION
TRAVASOL 4.25% IN DEXTROSE 5% IN PLASTIC CONTAINER

	BAXTER	4.25%;5GM/100ML	N19520 006 SEP 23, 1988

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE

/BP/	/CORD/LABS/	/100MG/	/N85261/003/
	ə CORD LABS	100MG	N85261 003

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

/AB/	/PBI/	/25MG/	/N87775/001/ /FEB/10,/1982/
	ə PBI	25MG	N87775 001 FEB 10, 1982
/AB/	/ROXANE/LABS/	/10MG/	/N86144/001/
/AB/		/25MG/	/N86145/001/
/AB/		/50MG/	/N86143/001/
/AB/		/75MG/	/N86147/001/
/AB/		/100MG/	/N86146/001/
/AB/		/150MG/	/N86148/001/
	ə ROXANE LABS	10MG	N86144 001
	ə	25MG	N86145 001
	ə	50MG	N86143 001
	ə	75MG	N86147 001
	ə	100MG	N86146 001
	ə	150MG	N86148 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

>DLT >/AB/	/VANGARD/LABS/	/10MG/	/N87632/001/ /FEB/01,/1982/
>DLT >			
>DLT >/AB/		/25MG/	/N87570/001/ /FEB/08,/1982/
>DLT >			
>DLT >/AB/		/50MG/	/N87616/001/ /FEB/08,/1982/
>DLT >			
>DLT >/AB/		/75MG/	/N87617/001/ /FEB/05,/1982/
>DLT >			
>DLT >/AB/		/100MG/	/N87639/001/ /FEB/08,/1982/
>DLT >			
>ADD >	ə VANGARD LABS	10MG	N87632 001 FEB 01, 1982
>ADD >			
>ADD >	ə	25MG	N87570 001 FEB 08, 1982
>ADD >			
>ADD >	ə	50MG	N87616 001 FEB 08, 1982
>ADD >			
>ADD >	ə	75MG	N87617 001 FEB 05, 1982
>ADD >			
>ADD >	ə	100MG	N87639 001 FEB 08, 1982
>ADD >			

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

AB	DANBURY PHARMA	10MG;2MG	N72539 001 FEB 15, 1989
AB		10MG;4MG	N72540 001 FEB 15, 1989
AB		25MG;2MG	N72541 001 FEB 15, 1989
AB		25MG;4MG	N72134 001 FEB 15, 1989
AB		50MG;4MG	N72135 001 FEB 15, 1989

AMMONIUM LACTATE

LOTION; TOPICAL
LAC-HYDRIN

	/BRISTOL/MYERS/	/EQ/12%/ACID/	/N19155/001/ /APR/24,/1985/
	WESTWOOD PHARMS	EQ 12% ACID	N19155 001 APR 24, 1985

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB	TAG PHARMS	250MG¤	N63030 001 FEB 28, 1989	
AB		500MG¤	N63031 001 FEB 28, 1989	

POWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN

AB	NOVOPHARM	250MG/5ML¤	N63001 001 JAN 06, 1989

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
AMPICILLIN

AB	CLONMEL CHEMS	EQ 125MG BASE/5ML¤	N62982 001 FEB 10, 1989
AB		EQ 250MG BASE/5ML¤	N62982 002 FEB 10, 1989

/TABLET;/CHEWABLE;/ORAL/
/POLYCILLIN;/

	/BRISTOL/LABS/	/EQ/125MG/BASE/	/N50093/001/
	@ BRISTOL LABS	EQ 125MG BASE	N50093 001

ASPIRIN; CARISOPRODOL

TABLET; ORAL
CARISOPRODOL AND ASPIRIN

> ADD >				
> ADD >	AB	PAR PHARM	325MG;200MG¤	N89594 001 MAR 31, 1989
> ADD >				

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE

/AA/	/LEDERLE/LABS/	/0.025MG;2.5MG/	/N86950/001/
	@ LEDERLE LABS	0.025MG;2.5MG	N86950 001

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

/AA/	/PBI/	/0.025MG;2.5MG/	/N87842/001/ /MAR/29,/1982/
	@ PBI	0.025MG;2.5MG	N87842 001 MAR 29, 1982

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
/LO-TROL/

/AA/	/VANGARD/LABS/	/0.025MG;2.5MG/	/N88009/001/ /MAR/25,/1983/
	@ VANGARD LABS	0.025MG;2.5MG	N88009 001 MAR 25, 1983

BENZONATATE

CAPSULE; ORAL
TESSALON

> DLT >		/DUPONT/PHARMS/	/100MG/	/N11210/001/
> ADD >		FOREST LABS	100MG	N11210 001

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE

AA	INVAMED	0.5MG¤	N72264 001 FEB 27, 1989
AA		1MG¤	N72265 001 FEB 27, 1989
AA		2MG¤	N72266 001 FEB 27, 1989

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

> DLT >	/AA/	/WHITE/TN/PAULSN/	/30MG/	/N83337/001/
> ADD >		@ WHITE TN PAULSN	30MG	N83337 001

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

SOLUTION; INTRAPERITONEAL
DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

> ADD >	AT	BAXTER	18.3MG/100ML;1.5GM/100ML;	
> ADD >			5.08MG/100ML;538MG/100ML;	
> ADD >			448MG/100ML	N17512 004
> DLT >	/AT/		/25.7MG/100ML;1.5GM/100ML;/	
> DLT >			/5.08MG/100ML;538MG/100ML;/	
> DLT >			/448MG/100ML/	/N17512/004/

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

>DLT >	/AP/	/CUTTER/BIOL/	/20MG/100ML;30MG/100ML;600MG/100ML;/ /310MG/100ML/	/N18417/001/
>ADD >		ə CUTTER BIOL	20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML	N18417 001

>AOD >	CARBOPLATIN			
>ADD >	INJECTABLE; INJECTION			
>ADD >	PARAPLATIN			
>AOD >	BRISTOL MYERS	50MG/VIAL¤	N19880 001	
>ADD >			MAR 03, 1989	
>ADD >		150MG/VIAL¤	N19880 002	
>AOD >			MAR 03, 1989	
>AOD >		450MG/VIAL¤	N19880 003	
>AOD >			MAR 03, 1989	

>OLT >	/CARBOPROST/			
>DLT >	/INJECTABLE;/INJECTION/			
>OLT >	/PROSTIN/15M/			
>DLT >	/UPJOHN/	/EQ/0.25MG/BASE/ML/	/N17989/001/	

>AOO >	CARBOPROST TROMETHAMINE		
>ADD >	INJECTABLE; INJECTION		
>AOD >	HEBAMATE		
>ADO >	UPJOHN	EQ 0.25MG BASE/ML	N17989 001

CEFAOROXIL

CAPSULE; ORAL

CEFADROXIL

AB	BIOCRAFT LABS	EQ 500MG BASE¤	N62695 001
			FEB 10, 1989
AB	PUREPAC PHARM	EQ 500MG BASE¤	N63017 001
			JAN 05, 1989

CEFADROXIL

POWOER FOR RECONSTITUTION; ORAL

CEFADROXIL

>ADO >	AB	BIOCRAFT LABS	EQ 125MG BASE/5ML¤	N62698 001
>AOD >				MAR 01, 1989
>AOD >	AB		EQ 250MG BASE/5ML¤	N62698 002
>ADD >				MAR 01, 1989
>ADD >	AB		EQ 500MG BASE/5ML¤	N62698 003
>ADD >				MAR 01, 1989

ULTRACEF

>ADD >	AB	BRISTOL LABS	EQ 125MG BASE/5ML	N62334 001
>ADD >	AB		EQ 125MG BASE/5ML	N62376 001
>ADD >				MAR 16, 1982
>ADD >	AB		EQ 250MG BASE/5ML	N62334 002
>ADD >	AB		EQ 250MG BASE/5ML	N62376 002
>ADD >				MAR 16, 1982

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

>ADD >	AP	TAG PHARMS	EQ 250MG BASE/VIAL¤	N63016 001
>ADD >				MAR 14, 1989
>ADD >	AP		EQ 500MG BASE/VIAL¤	N63016 002
>ADD >				MAR 14, 1989
>ADD >	AP		EQ 1GM BASE/VIAL¤	N63016 003
>ADD >				MAR 14, 1989

CEFPIRAMIDE SODIUM

INJECTABLE; INJECTION

CEFPIRAMIDE SODIUM

	WYETH AYERST LABS	EQ 1GM BASE/VIAL¤	N50633 002
			JAN 31, 1989
		EQ 2GM BASE/VIAL¤	N50633 003
			JAN 31, 1989
		EQ 10GM BASE/VIAL¤	N50633 005
			JAN 31, 1989

CEPHALEXIN

TABLET; ORAL

CEPHALEXIN

AB	BIOCRAFT LABS	EQ 250MG BASE¤	N63023 001
			JAN 12, 1989
AB		EQ 500MG BASE¤	N63024 001
			JAN 12, 1989

CERULETIDE DIETHYLAMINE

>DLT>	/INJECTABLE;/INJECTION/			
>DLT>	/TYMTRAN/			
>DLT>	/ADRIA/LABS/	/0.02MG/ML/	/N18296/001/	
>ADD>	a ADRIA LABS	0.02MG/ML	N18296 001	

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

	CHLORDIAZEPOXIDE HCL			
/AA/	/VANGARD/LABS/	/5MG/	/N88129/001/	/MAR/28,/1983/
/AA/		/10MG/	/N88010/001/	/MAR/28,/1983/
/AA/		/25MG/	/N88130/001/	/MAR/28,/1983/
	a VANGARD LABS	5MG	N88129 001	MAR 28, 1983
	a	10MG	N88010 001	MAR 28, 1983
	a	25MG	N88130 001	MAR 28, 1983

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

	CHLORPHENIRAMINE MALEATE			
/AA/	/LEDERLE/LABS/	/4MG/	/N86941/001/	
	a LEDERLE LABS	4MG	N86941 001	

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL			
AB	CORD LABS	12MG;75MG	N88940 001	JAN 26, 1989
	ORNADE			
AB /BC/	SK&F LABS	12MG;75MG /12MG;75MG/	N12152 004 /N12152/004/	

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL

	TUSSIONEX			
>ADD>	FISONS	EQ 8MG MALEATE/5ML;		
>ADD>		EQ 10MG BITARTRATE/5ML	N19111 001	DEC 31, 1987
>ADD>				

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL

	TUSSIONEX			
>DLT>	/PENNWALT/	/EQ/8MG/MALEATE/5ML;/		
>DLT>		/EQ/10MG/BITARTRATE/5ML/	/N19111/001/	/DEC/31,/1987/
>DLT>				

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL

	CHLORPROMAZINE HCL			
/BP/	/VANGARD/LABS/	/10MG/	/N88038/001/	/AUG/16,/1982/
/BP/		/25MG/	/N87645/001/	
/BP/		/50MG/	/N87646/001/	
	a VANGARD LABS	10MG	N88038 001	AUG 16, 1982
	a	25MG	N87645 001	
	a	50MG	N87646 001	

CHLORTHALIDONE

TABLET; ORAL

	CHLORTHALIDONE			
/AA/	/VANGARD/LABS/	/25MG/	/N88012/001/	/JUL/14,/1982/
/AA/		/50MG/	/N88073/001/	/MAR/25,/1983/
	a VANGARD LABS	25MG	N88012 001	JUL 14, 1982
	a	50MG	N88073 001	MAR 25, 1983

CHLORZOXAZONE

TABLET; ORAL

	CHLORZOXAZONE			
>DLT> /AA/	/CHELSEA/LABS/	/250MG/	/N86948/001/	/AUG/09,/1982/
>DLT>				
>ADD>	a CHELSEA LABS	250MG	N86948 001	AUG 09, 1982
>ADD>				
AA	PIONEER PHARMS	250MG¤	N89592 001	JAN 06, 1989
AA		500MG¤	N89948 001	JAN 06, 1989

CHYMOPAPAIN

INJECTABLE; INJECTION
CHYMODIACTIN

> DLT >	/BAXTER/	/4,000/UNITS/VIAL/	/N18663/002/	
> DLT >			/AUG/21,/1984/	
> DLT >		/10,000/UNITS/VIAL/	/N18663/001/	
> DLT >			/NOV/10,/1982/	
> ADD >	BOOTS (USA)	4,000 UNITS/VIAL	N18663 002	
> ADD >			AUG 21, 1984	
> ADD >		10,000 UNITS/VIAL	N18663 001	
> ADD >			NOV 10, 1982	
	/DISCASE/			
	/BOOTS/PHARMS/	/12,500/UNITS/VIAL/	/N18625/001/	
			/JAN/18,/1984/	
	ə BOOTS PHARMS	12,500 UNITS/VIAL	N18625 001	
			JAN 18, 1984	

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

AP	ASTRA PHARM PROOS	EQ 150MG BASE/ML*	N62928 001
			FEB 13, 1989
AP	DUPONT CRI CARE	EQ 150MG BASE/ML*	N62908 001
			FEB 01, 1989

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

AT	COPLEY PHARM	EQ 1% BASE*	N62944 001
			JAN 11, 1989

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

/AB/	/LEDERLE/LABS/	/3.75MG/	/N72013/001/
			/DEC/15,/1987/
/AB/		/7.5MG/	/N72014/001/
			/DEC/15,/1987/
/AB/		/15MG/	/N72015/001/
			/DEC/15,/1987/
	ə LEDERLE LABS	3.75MG	N72013 001
			DEC 15, 1987
	ə	7.5MG	N72014 001
			DEC 15, 1987
	ə	15MG	N72015 001
			DEC 15, 1987

CYANOCOBALAMIN

INJECTABLE; INJECTION

> DLT >	/REDISOL/			
> DLT >	/AP/ /MS&D/	/1MG/ML/	/N06668/010/	
> ADD >	ə MS&D	1MG/ML	N06668 010	
> DLT >	/VI-TWEL/			
> DLT >	/AP/ /BERLEX/LABS/	/1MG/ML/	/N07012/002/	
> ADD >	ə BERLEX LABS	1MG/ML	N07012 002	

DEMECLOCYCLINE HYDROCHLORIDE

/SYRUP;/ORAL/			
/DECLOMYCIN;/			
/LEDERLE/LABS/	/75MG/5ML/		/N50257/001/
ə LEDERLE LABS	75MG/5ML		N50257 001

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
DICYCLOMINE HCL

AB	PIONEER PHARMS	10MG*	N89361 001
			JAN 10, 1989

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL
HETRAZAN

> DLT >	/3/LEDERLE/LABS/	/50MG/		/N06459/001/
> ADD >	LEDERLE LABS	50MG		N06459 001

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM SR

MARION LABS	60MG*	N19471 001
		JAN 23, 1989
	90MG*	N19471 002
		JAN 23, 1989
	120MG*	N19471 003
		JAN 23, 1989
ə	180MG*	N19471 004
		JAN 23, 1989

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

/AA/	/VANGARD/LABS/	/25MG/	/N88034/001/	
			/OCT/27,/1982/	
/AA/		/50MG/	/N87630/001/	
	@ VANGARD LABS	25MG	N88034 001	
			OCT 27, 1982	
	@	50MG	N87630 001	
>DLT >/AA/	/WHITE/TN/PAULSN/	/50MG/	/N80800/001/	
>ADD >	@ WHITE TN PAULSN	50MG	N80800 001	

ELIXIR; ORAL

DIPHENHYDRAMINE HCL

/AA/	/PRIVATE/FMLTNS/	/12.5MG/5ML/	/N85287/001/
	@ PRIVATE FMLTNS	12.5MG/5ML	N85287 001

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

AP	ABBOTT LABS	40MG/ML*	N70656 001
			JAN 24, 1989
AP		80MG/ML*	N70657 001
			JAN 24, 1989

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIN HCL

>ADD > AB	QUANTUM PHARMCS	EQ 100MG BASE*	N72375 001	
>ADD >			MAR 15, 1989	
>ADD > AB		EQ 150MG BASE*	N72376 001	
>ADD >			MAR 15, 1989	

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DOXORUBICIN HCL

>ADD > AP	CETUS BEN VENUE	2MG/ML*	N62975 001	
>ADD >			MAR 17, 1989	
>ADD > AP		10MG/VIAL*	N62921 001	
>ADD >			MAR 17, 1989	
>ADD > AP		20MG/VIAL*	N62921 002	
>ADD >			MAR 17, 1989	
>ADD > AP		50MG/VIAL*	N62921 003	
>ADD >			MAR 17, 1989	

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

DOXYCYCLINE HYCLATE

AP	LEDERLE PARNTLS	EQ 10DMG BASE/VIAL*	N62992 001
			FEB 16, 1989
AP		EQ 200MG BASE/VIAL*	N62992 002
			FEB 16, 1989

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

/AA/	/LEDERLE/LABS/	/0.5MG/	/N86984/001/	
/AA/		/1MG/	/N86985/001/	
	@ LEDERLE LABS	0.5MG	N86984 001	
	@	1MG	N86985 001	
/AA/	/VANGARD/LABS/	/0.5MG/	/N88013/001/	
			/SEP/20,/1982/	
/AA/		/1MG/	/N88014/001/	
			/SEP/20,/1982/	
	@ VANGARD LABS	0.5MG	N88013 001	
			SEP 20, 1982	
	@	1MG	N88014 001	
			SEP 20, 1982	

DDXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

>ADD > AP	AORIA LABS	2MG/ML	N50629 002
>ADD >			MAY 03, 1988
>ADD > AP		2MG/ML	N50629 001
>ADD >			DEC 23, 1987

ADRIAMYCIN RDF

>ADD > AP	ADRIA LABS	10MG/VIAL	N50467 001
>ADD > AP		20MG/VIAL	N50467 003
>ADD >			MAY 20, 1985
>ADD > AP		50MG/VIAL	N50467 002

ESTROGENS, ESTERIFIED

TABLET; ORAL

FEMOGEN

/BS/	/PRIVATE/FMLTNS/	/2.5MG/	/N85007/001/
	@ PRIVATE FMLTNS	2.5MG	N85007 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORCEPT-E 1/35 21
AB GYNOPHARMA 0.035MG;1MG N71545 001 FEB 09, 1989

TABLET; ORAL-28
NORCEPT-E 1/35 28
AB GYNOPHARMA 0.035MG;1MG N71546 001 FEB 09, 1989

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
AB LEMMON 0.05% N72488 001 FEB 06, 1989
AB 0.05% N72490 001 FEB 07, 1989

VASODERM E
AB TJ ROACO 0.05% N72494 001 JAN 19, 1989

GEL; TOPICAL
FLUOCINONIDE
AB LEMMON 0.05% N72537 001 FEB 07, 1989

LIDEX
A8 SYNTEX LA8S 0.05% N17373 001

SOLUTION; TOPICAL
FLUOCINONIDE
AT LEMMON 0.05% N72511 001 FEB 07, 1989

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM MCL
> ADD > AB CHELSEA LABS 15MG N72368 001 MAR 30, 1989
> ADD > AB 30MG N72369 001 MAR 30, 1989

FLUTAMIDE

CAPSULE; ORAL
EULEXIN
SCHERING 125MG N18554 001 JAN 27, 1989

FOLIC ACID

TA8LET; ORAL
FOLIC ACID
/AA/ /PBI/ /1MG/ /N87828/001/ /MAY/13,/1982/
a PBI 1MG N87828 001 MAY 13, 1982
> OLI >/AA/ /WHITE/TN/PAULSN/ /1MG/ /N80691/002/
> ADD > a WHITE TN PAULSN 1MG N80691 002

GEMFIBROZIL

CAPSULE; ORAL
LOPID
/PARKE/DAVIS/ /200MG/ /N18422/001/
a PARKE DAVIS 200MG N18422 001

TABLET; ORAL
LOPID
PARKE DAVIS 600MG N18422 003 NOV 20, 1986

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER
AP BAXTER 4,000 UNITS/100ML N18814 001 OCT 31, 1983
HEPARIN SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABS 4,000 UNITS/100ML N19805 001 JAN 25, 1989
HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABS 5,000 UNITS/100ML N19805 002 JAN 25, 1989

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

/AA/	/PBI/	/25MG/	/N87780/001/ /MAR/29,/1982/	
/AA/		/50MG/	/N87751/001/ /MAR/29,/1982/	
	ə PBI	25MG	N87780 001 MAR 29, 1982	
	ə	50MG	N87751 001 MAR 29, 1982	

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/	/PBI/	/25MG/	/N87827/001/ /APR/19,/1982/	
/AB/		/50MG/	/N87752/001/ /APR/19,/1982/	
	ə PBI	25MG	N87827 001 APR 19, 1982	
	ə	50MG	N87752 001 APR 19, 1982	
/AB/	/VANGARD/LABS/	/25MG/	/N87638/001/	
/AB/		/50MG/	/N87610/001/	
	ə VANGARD LABS	25MG	N87638 001	
	ə	50MG	N87610 001	
>DLT >/AB/	/WHITE/TN/PAULSN/	/25MG/	/N83809/002/	
>DLT >/AB/		/50MG/	/N83809/001/	
>ADD >	WHITE TN PAULSN	25MG	N83809 002	
>ADD >	ə	50MG	N83809 001	

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL

PRINZIDE 12.5

MS&D RES LABS	12.5MG;20MG¤	N19778 001 FEB 16, 1989

PRINZIDE 25

MS&D RES LABS	25MG;20MG¤	N19778 002 FEB 16, 1989

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	DANBURY PHARMA	15MG;250MG¤	N70958 001 FEB 06, 1989
AB		25MG;250MG¤	N70959 001 JAN 19, 1989
AB		30MG;500MG¤	N71069 001 JAN 19, 1989
AB		50MG;500MG¤	N70960 001 FEB 06, 1989

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

>DLT >	/H.R.-50;/			
>DLT > /BP/	/WHITE/TN/PAULSN/	/50MG;0.125MG/	/N85338/001/	
>ADD >	ə WHITE TN PAULSN	50MG;0.125MG	N85338 001	

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

/AB/	/PBI/	/25MG;25MG/	/N87651/001/
	ə PBI	25MG;25MG	N87651 001
/AB/	/VANGARD/LABS/	/25MG;25MG/	/N87655/001/
	ə VANGARD LABS	25MG;25MG	N87655 001

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

AT	NMC LABS	2.5%	N89754 001 FEB 01, 1989
AT	TOPIDERM	1%	N89273 001 FEB 17, 1989

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE

AT	PARKE DAVIS	1%	N89914 001 JAN 03, 1989

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

/AB/	/PBI/	/25MG/	/N87776/001/	/FEB/10,/1982/
	ə PBI	25MG	N87776 001	FEB 10, 1982
/AB/	/VANGARD/LABS/	/10MG/	/N88036/001/	/NOV/03,/1982/
/AB/		/25MG/	/N87619/001/	/FEB/09,/1982/
/AB/		/50MG/	/N87631/001/	/JAN/04,/1982/
	ə VANGARD LABS	10MG	N88036 001	NOV 03, 1982
	ə	25MG	N87619 001	FEB 09, 1982
	ə	50MG	N87631 001	JAN 04, 1982

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

> ADD > AB	INWOOD LABS	75MG¤	N72410 001	MAR 15, 1989

LACTULOSE

SYRUP; ORAL
DUPHALAC

> ADD > AA	REID ROWELL	10GM/15ML¤	N72372 001	MAR 22, 1989

SYRUP; ORAL, RECTAL
PORTALAC

> ADD > AA	REID ROWELL	10GM/15ML¤	N72374 001	MAR 22, 1989

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
WELLCOVORIN

AP	BURROUGHS WELLC	EQ 50MG BASE/VIAL¤	N89465 001	JAN 23, 1989
AP		EQ 100MG BASE/VIAL¤	N89834 001	JAN 23, 1989
		EQ 25MG BASE/VIAL¤	N89833 001	JAN 23, 1989

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON DEPOT

	TAP PHARMS	7.5MG/VIAL¤	N19732 001	JAN 26, 1989

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
XYLOCAINE

AP	ASTRA PHARM PRODS	1%	N16801 005	JAN 19, 1988

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

AB	PBI	300MG¤	N72542 001	FEB 01, 1989

MANNITOL

SOLUTION; IRRIGATION
/RESECTISOL;/

/KENDALL/MCGAW/	/5GM/100ML/	/N16704/002/	
ə KENDALL MCGAW	5GM/100ML	N16704 002	

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
MECLIZINE HCL

/AA/	/VANGARD/LABS/	/12.5MG/	/N87877/001/	/APR/20,/1982/
/AA/		/25MG/	/N87620/001/	/JAN/04,/1982/
	ə VANGARD LABS	12.5MG	N87877 001	APR 20, 1982
	ə	25MG	N87620 001	JAN 04, 1982

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM

>ADD >	AB	BARR LABS	EQ 50MG BASE¤	N72848 001	
>ADD >				MAR 20, 1989	
>ADD >	AB		EQ 100MG BASE¤	N72809 001	
>ADD >				MAR 20, 1989	

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL

>ADD >	AP	ASTRA PHARM PRODS	25MG/ML¤	N89781 001	
>ADD >				MAR 31, 1989	
>ADD >	AP		50MG/ML¤	N89782 001	
>ADD >				MAR 31, 1989	
>ADD >	AP		50MG/ML¤	N89783 001	
>ADD >				MAR 31, 1989	
>ADD >	AP		50MG/ML¤	N89784 001	
>ADD >				MAR 31, 1989	
>ADD >	AP		75MG/ML¤	N89785 001	
>ADD >				MAR 31, 1989	
>ADD >	AP		100MG/ML¤	N89786 001	
>ADD >				MAR 31, 1989	
>ADD >	AP		100MG/ML¤	N89787 001	
>ADD >				MAR 31, 1989	
>ADD >	AP		100MG/ML¤	N89788 001	
>ADD >				MAR 31, 1989	

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE

>DLT >/AA/		/LEDERLE/LABS/	/400MG/	/N86299/001/	
>ADD >		a LEDERLE LABS	400MG	N86299 001	
/AA/		/VANGARD/LABS/	/400MG/	/N88011/001/	
				/JUL/14/1982/	
		a VANGARD LABS	400MG	N88011 001	
				JUL 14, 1982	
>DLT >/AA/		/WHITE/TN/PAULSN/	/200MG/	/N83830/001/	
>DLT >/AA/			/400MG/	/N83442/001/	
>ADD >		a WHITE TN PAULSN	200MG	N83830 001	
>ADD >		a	400MG	N83442 001	

MESNA

INJECTABLE; INJECTION
MESNEX

>ADD >		ASTA PHARMA	100MG/ML	N19884 001	
>ADD >				DEC 30, 1988	
>DLT >		/BRISTOL/MYERS/	/100MG/ML/	/N19884/001/	
>DLT >				/DEC/30/1988/	

METHYLPREDNISOLONE ACETATE

/ENEMA;/RECTAL/
/MEDROL;/

		/UPJOHN/	/40MG/BOT/	/N18102/001/	
		a UPJOHN	40MG/BOT	N18102 001	

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

	AP	BULL LABS	EQ 10MG BASE/2ML¤	N71990 001	
				JAN 18, 1989	
>ADD >	AP	DUPONT CRI CARE	EQ 10MG BASE/2ML¤	N71291 001	
>ADD >				MAR 03, 1989	

METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR

	AB	GEIGY PHARMS	50MG	N17963 001
	AB		100MG	N17963 002
		METOPROLOL TARTRATE		
	AB	HENRY SCHEIN	50MG¤	N71690 001 †
				FEB 08, 1989
	AB		100MG¤	N71691 001 †
				FEB 08, 1989

MOMETASONE FUROATE

LOTION; TOPICAL
ELOCON

>ADD >		SCHERING	0.1%	N19796 001
>ADD >				MAR 30, 1989

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

AP	ABBOTT LABS	10MG/ML*	N70914 001 FEB 03, 1989	
AP		10MG/ML*	N70915 001 FEB 03, 1989	
AP		20MG/ML*	N70916 001 FEB 03, 1989	
AP		20MG/ML*	N70917 001 FEB 03, 1989	
AP		20MG/ML*	N70918 001 FEB 03, 1989	

OXACILLIN SODIUM

INJECTABLE; INJECTION
OXACILLIN SODIUM

AP	ELKINS SINN	EQ 250MG BASE/VIAL*	N62711 001 FEB 03, 1989
AP		EQ 500MG BASE/VIAL*	N62711 002 FEB 03, 1989
AP		EQ 1GM BASE/VIAL*	N62711 003 FEB 03, 1989
AP		EQ 2GM BASE/VIAL*	N62711 004 FEB 03, 1989
AP		EQ 4GM BASE/VIAL*	N62711 005 FEB 03, 1989
AP		EQ 10GM BASE/VIAL*	N62711 006 FEB 03, 1989

PANCURONIUM BROMIDE

INJECTABLE; INJECTION
PANCURONIUM BROMIDE

AP	ABBOTT LABS	1MG/ML*	N72320 001 JAN 19, 1989
AP		2MG/ML*	N72321 001 JAN 19, 1989

PENBUTOLOL SULFATE

TABLET; ORAL
LEVATOL

> DLT >	/LILLY/	/10MG/	/N18976/001/	
> DLT >			/DEC/30,/1987/	
> ADD >	REED & CARNRICK	10MG	N18976 001 DEC 30, 1987	
> ADD >				

PENICILLIN G BENZATHINE

/SUSPENSION;/ORAL/
/BICILLIN/

	/WYETH/AYERST/LABS/	/300,000/UNITS/5ML/	/N50126/002/
	@ WYETH AYERST LABS	300,000 UNITS/5ML	N50126 002

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN V POTASSIUM

AA	CLONMEL CHEMS	EQ 125MG BASE/5ML*	N62981 001 FEB 10, 1989
AA		EQ 250MG BASE/5ML*	N62981 002 FEB 10, 1989

PENTOBARBITAL SODIUM

CAPSULE; ORAL
PENTOBARBITAL SODIUM

> DLT >/AA/	/WHITE/TN/PAULSN/	/100MG/	/N83338/001/	
> ADD >	@ WHITE TN PAULSN	100MG	N83338 001	

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
/DI-METREX/

/AA/	/PRIVATE/FMLTNS/	/35MG/	/N85698/001/
	@ PRIVATE FMLTNS	35MG	N85698 001

PHENDIMETRAZINE TARTRATE

/AA/	/PRIVATE/FMLTNS/	/35MG/	/N85199/001/
	@ PRIVATE FMLTNS	35MG	N85199 001

PHENYL AMINOSALICYLATE

> DLT >	/POWDER;/ORAL/		
> DLT >	/PHENY-PAS-TEBAMIN/		
> DLT >	/PURDUE/FRDRK/	/50%/	/N11695/002/
> ADD >	@ PURDUE FRDRK	50%	N11695 002
> DLT >	/TABLET;/ORAL/		
> DLT >	/PHENY-PAS-TEBAMIN/		
> DLT >	/PURDUE/FRDRK/	/500MG/	/N11695/003/
> ADD >	@ PURDUE FRDRK	500MG	N11695 003

> ADD > PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

> ADD > SOLUTION/DROPS; OPHTHALMIC
> ADD > PREFRIN-A
> ADD > ALLERGAN PHARMS 0.12%;0.1% N07953 001

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN
PLASTIC CONTAINER
/AP/ /BAXTER/ /75MG/100ML;900MG/100ML/ /N17648/004/
BAXTER 75MG/100ML;900MG/100ML N17648 004
/AP/ /KENDALL/MCGAW/ /75MG/100ML;900MG/100ML/ /N18722/001/
/NOV/09/1982/
@ KENDALL MCGAW 75MG/100ML;900MG/100ML N18722 001
NOV 09, 1982

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN
PLASTIC CONTAINER
/AP/ /KENDALL/MCGAW/ /150MG/100ML;/
/900MG/100ML/ /N18722/002/
/NOV/09/1982/
@ KENDALL MCGAW 150MG/100ML;
900MG/100ML N18722 002
NOV 09, 1982

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN
PLASTIC CONTAINER
/AP/ /KENDALL/MCGAW/ /220MG/100ML;/
/900MG/100ML/ /N18722/003/
/NOV/09/1982/
@ KENDALL MCGAW 220MG/100ML;
900MG/100ML N18722 003
NOV 09, 1982

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN
PLASTIC CONTAINER
/AP/ /KENDALL/MCGAW/ /300MG/100ML;/
/900MG/100ML/ /N18722/004/
/NOV/09/1982/
@ KENDALL MCGAW 300MG/100ML;
900MG/100ML N18722 004
NOV 09, 1982

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
PRAZOSIN HCL
AB DANBURY PHARMA EQ 1MG BASE N72352 001
MAY 16, 1989 : JAN 11, 1989
AB EQ 2MG BASE N72333 001
MAY 16, 1989 : JAN 11, 1989
AB EQ 5MG BASE N72609 001
MAY 16, 1989 : JAN 11, 1989
> ADD > AB LEDERLE LABS EQ 1MG BASE N72705 001
> ADD > MAY 16, 1989 : MAR 15, 1989
> ADD > AB EQ 2MG BASE N72706 001
> ADD > MAY 16, 1989 : MAR 15, 1989
> ADD > AB EQ 5MG BASE N72707 001
> ADD > MAY 16, 1989 : MAR 15, 1989
AB MYLAN PHARMS EQ 1MG BASE N72573 001
MAY 16, 1989 : FEB 28, 1989
AB EQ 2MG BASE N72574 001
MAY 16, 1989 : FEB 28, 1989
AB EQ 5MG BASE N72575 001
MAY 16, 1989 : FEB 28, 1989
> DLT >/AB/ /ZENITH/LABS/ /EQ 1MG BASE/ /N71994/001/
> DLT > /SEP/12/1988/
> ADD > AB ZENITH LABS EQ 1MG BASE N71994 001
> ADD > MAY 16, 1989 : SEP 12, 1988
> DLT >/AB/ /EQ 2MG BASE/ /N71995/001/
> DLT > /SEP/12/1988/
> ADD > AB EQ 2MG BASE N71995 001
> ADD > MAY 16, 1989 : SEP 12, 1988
> DLT >/AB/ /EQ 5MG BASE/ /N71745/001/
> DLT > /SEP/12/1988/
> ADD > AB EQ 5MG BASE N71745 001
> ADD > MAY 16, 1989 : SEP 12, 1988

PREDNISOLONE

SYRUP; ORAL
PRELONE
MURD PHARM 5MG/5ML N89654 001
JAN 17, 1989

TABLET; ORAL
PREDNISOLONE
> DLT > /BX/ /WHITE/TN/PAULSN/ /5MG/ /N80342/001/
> ADD > @ WHITE TN PAULSN 5MG N80342 001

PREDNISONE

SOLUTION; ORAL

PREDNISONE INTENSOL

	ROXANE LABS	5MG/ML	N88810 001 FEB 20, 1985	
/SYRUP;/ORAL/	/PREDNISONE/INTENSOL/ /ROXANE/LABS/	/5MG/ML/	/N88810/001/ /FEB/20,/1985/	

TABLET; ORAL

DELTASONE

AB /BX/	UPJOHN	50MG /50MG/	N09986 0D8 /N09986/008/	

PREDNISONE

AB	CORD LABS	10MG	N89983 001 JAN 12, 1989	
AB		50MG	N89984 001 JAN 12, 1989	
/BX/	/VANGARD/LABS/	/5MG/	/N87682/001/ /JAN/15,/1982/	
/BX/		/20MG/	/N87701/001/ /JAN/15,/1982/	
	ə VANGARD LABS	5MG	N87682 001 JAN 15, 1982	
	ə	20MG	N87701 001 JAN 15, 1982	
>DLT > /BX/	/WHITE/TN/PAULSN/	/5MG/	/N80343/001/	
>ADD >	ə WHITE TN PAULSN	5MG	N80343 001	
>DLT >	/SERVISONE/			
>DLT > /BX/	/LEDERLE/LABS/	/5MG/	/N80223/001/	
>ADD >	ə LEDERLE LABS	5MG	N80223 001	

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

PROCAINAMIDE HCL

/AB/	/VANGARD/LABS/	/250MG/	/N87643/001/ /JUN/01,/1982/	
/AB/		/500MG/	/N87875/001/ /JUN/01,/1982/	
	ə VANGARD LABS	250MG	N87643 001 JUN 01, 1982	
	ə	500MG	N87875 001 JUN 01, 1982	

TABLET, EXTENDED RELEASE; ORAL

PROCAINAMIDE HCL

>ADD > AB	INWOOD LABS	500MG	N89840 001	
>ADD >			MAR 06, 1989	

PROPRANOLOL HYDROCHLORIDE

SOLUTION; ORAL

PROPRANOLOL HCL

>ADD > AA	PBI	20MG/5ML	N71984 001 MAR 03, 1989	
>ADD > AA		40MG/5ML	N71985 001 MAR 03, 1989	
>ADD > AA	ROXANE LABS	20MG/5ML	N70979 001 MAY 15, 1987	
>ADD > AA		40MG/5ML	N70690 001 MAY 15, 1987	

TABLET; ORAL

PROPRANOLOL HCL

/AB/	/LEDERLE/LABS/	/10MG/	/N72117/001/ /JUN/23,/1988/	
/AB/		/20MG/	/N72118/001/ /JUN/23,/1988/	
/AB/		/40MG/	/N72119/001/ /JUN/23,/1988/	
/AB/		/80MG/	/N72120/001/ /JUN/23,/1988/	
	ə LEDERLE LABS	10MG	N72117 001 JUN 23, 1988	
	ə	20MG	N72118 001 JUN 23, 1988	
	ə	40MG	N72119 001 JUN 23, 1988	
	ə	80MG	N72120 001 JUN 23, 1988	

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

MESTINON

>ADD > AP	ICN PHARMS	5MG/ML	ND9830 001	
>DLT >/AP/	/ROCHE/	/5MG/ML/	/N09830/001/	

SYRUP; ORAL

MESTINON

>ADD >	ICN PHARMS	60MG/5ML	N15193 001	
>DLT >	/ROCHE/	/60MG/5ML/	/N15193/001/	

TABLET; ORAL

MESTINON

>ADD >	ICN PHARMS	60MG	N09829 002	
>DLT >	/ROCHE/	/60MG/	/N09829/002/	

TABLET, EXTENDED RELEASE; ORAL

MESTINON

>ADD >	ICN PHARMS	180MG	N11665 001	

PYRIDOSTIGMINE BROMIDE

TABLET, EXTENDED RELEASE; ORAL
MESTINON
>DLT> /ROCHE/ /180MG/ /N11665/001/

QUINIDINE GLUCONATE

INJECTABLE; INJECTION
QUINIOINE GLUCONATE
/LILLY/ /80MG/ML/ /N07529/001/
LILLY 80MG/ML¤ N07529 002
FEB 10, 1989

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE
/AB/ /PBI/ /200MG/ /N87837/001/
/APR/14,/1982/
a PBI 200MG N87837 001
APR 14, 1982
>DLT>/AB/ /WHITE/TN/PAULSN/ /200MG/ /N85444/001/
>ADD> a WHITE TN PAULSN 200MG N85444 001

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM
>DLT>/AA/ /WHITE/TN/PAULSN/ /100MG/ /N85798/001/
>ADD> a WHITE TN PAULSN 100MG N85798 001

SECRETIN

INJECTABLE; INJECTION
SECRETIN-FERRING
FERRING LABS 75CU/VIAL N18290 001
/SECRETIN-KABI/
/PHARMACIA/LABS/ /75CU/VIAL/ /N18290/001/

SINCALIDE

INJECTABLE; INJECTION
KINEVAC
/SQUIBB/ /0.005MG/VIAL/ /N17697/001/
SQUIBB DIAGS 0.005MG/VIAL N17697 001

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
>DLT>/AP/ /CUTTER/BIOL/ /450MG/100ML/ /N18503/001/
>ADD> a CUTTER BIOL 450MG/100ML N18503 001
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
>DLT>/AP/ /CUTTER/BIOL/ /900MG/100ML/ /N18502/001/
>AOD> a CUTTER BIOL 900MG/100ML N18502 001

SOLUTION; IRRIGATION
>DLT> /SODIUM CHLORIDE IN PLASTIC CONTAINER/
>DLT>/AT/ /CUTTER/BIOL/ /900MG/100ML/ /N18247/001/
>ADD> a CUTTER BIOL 900MG/100ML N18247 001

SODIUM IODIDE, I-123

CAPSULE; ORAL
SODIUM IODIDE I 123
AA BENEDICT NUCLR 200 UCI N18671 002
MAY 27, 1982
AA MALLINCKRODT 100 UCI¤ N71909 001
FEB 28, 1989
AA 200 UCI¤ N71910 001
FEB 28, 1989

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
AA CARDLINA MED 454GM/BOT¤ N89910 001
JAN 19, 1989

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
/AB/ /VANGARD/LABS/ /25MG/ /N87648/001/
/FEB/01,/1982/
a VANGARD LABS 25MG N87648 001
FEB 01, 1982

SULCONAZOLE NITRATE

CREAM; TOPICAL
SULCOSYN
SYNTEX LABS 1%¤ N18737 001
FEB 28, 1989

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL
SODIUM PERTECHNETATE TC 99M

> ADD >	AP	CIS US	12MCI/ML		N17321 001
> ADD >	AP		24MCI/ML		N17321 002
> ADD >	AP		48MCI/ML		N17321 003
> DLT >	/AP/	/SYNCOR/INTL/	/12MCI/ML/		/N17321/001/
> DLT >	/AP/		/24MCI/ML/		/N17321/002/
> DLT >	/AP/		/48MCI/ML/		/N17321/003/

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION
THALLOUS CHLORIDE TL 201

> ADD >	AP	SQUIBB DIAGS	1MCI/ML		N18548 001
> ADD >					DEC 30, 1982

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL
THEO-DUR

> ADD >	AB	KEY PHARMS	100MG		N85328 001
> ADD >	AB		200MG		N86998 001
> DLT >	/BC/		/100MG/		/N85328/001/
> DLT >	/BC/		/200MG/		/N86998/001/

THEOPHYLLINE

> ADD >	AB	INWOOD LABS	100MG		N88320 001
> ADD >					FEB 21, 1985
> ADD >	AB		200MG		N88321 001
> ADD >					FEB 21, 1985
> DLT >	/BC/		/100MG/		/N88320/001/
> DLT >					/FEB/21,/1985/
> DLT >	/BC/		/200MG/		/N88321/001/
> DLT >					/FEB/21,/1985/

TIMOLOL MALEATE

TABLET; ORAL
BLOCADREN

	AB	MS&D	5MG		N18017 001
	AB		10MG		N18017 002
	AB		20MG		N18017 004

TIMOLOL MALEATE

> ADD >	AB	BOLAR PHARM	5MG¤		N72269 001
> ADD >				APR 11, 1989 :	MAR 14, 1989
> ADD >	AB		10MG¤		N72270 001
> ADD >				APR 11, 1989 :	MAR 14, 1989
> ADD >	AB		20MG¤		N72271 001
> ADD >				APR 11, 1989 :	MAR 14, 1989

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

AB	PBI	5MG¤			N72001 001
			APR 11, 1989 :		JAN 10, 1989
AB		10MG¤			N72002 001
			APR 11, 1989 :		JAN 10, 1989
AB		20MG¤			N72003 001
			APR 11, 1989 :		JAN 10, 1989

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

/AB/	/VANGARD LABS/	/500MG/		/N87876/001/
				/APR/20,/1982/
	∂ VANGARD LABS	500MG		N87876 001
				APR 20, 1982

TOLMETIN SODIUM

TABLET; ORAL

> ADD >	TOLECTIN 600			
> ADD >	MCNEIL PHARM	EQ 600MG BASE¤		N17628 002
> ADD >				MAR 08, 1989

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

AB	LEMMON	50MG¤		N72192 001
				FEB 02, 1989
AB		100MG¤		N72193 001
				FEB 02, 1989

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE

AT	TOPIDERM	0.025%¤		N89274 001
				FEB 21, 1989
AT		0.1%¤		N89275 001
				FEB 21, 1989
AT		0.5%¤		N89276 001
				FEB 21, 1989

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL
TRIHEXYPHENIDYL HCL

/AA/	/VANGARD LABS/	/2MG/	/N88035/001/ /JUL 30, 1982/
	@ VANGARD LABS	2MG	N88035 001 JUL 30, 1982

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

AB	MYLAN PHARMS	80MG	N71482 001 FEB 15, 1989
AB		120MG	N71483 001 FEB 15, 1989
AB	SIDMAK LABS	80MG	N72124 001 JAN 26, 1989
AB		120MG	N72125 001 JAN 26, 1989

WATER FOR IRRIGATION, STERILE

LIQUID; IRRIGATION
STERILE WATER IN PLASTIC CONTAINER

>OLT >/AT/	/CUTTER BIOL/	/100%/	/N18246/001/
>ADD >	@ CUTTER BIOL	100%	N18246 001

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G&W LABS 325MG N18060 003 DEC 18, 1986

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
> ADD > BIOSCRUB
> ADD > KW GRIFFEN 4% N19822 001 MAR 31, 1989

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
> ADD > PSEUDO-CHLOR
> ADD > KV PHARM 12MG;120MG N71455 001 MAR 01, 1989

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
PENNTUSS
> ADD > FISONS EQ 4MG MALEATE/5ML; EQ 10MG BASE/5ML N18928 001 AUG 14, 1985
> DLT > /PENNWALT/ /EQ/4MG/MALEATE/5ML;/ /EQ/10MG/BASE/5ML/ /N18928/001/ /AUG/14,/1985/

CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
CORSYM
> ADD > FISONS EQ 4MG MALEATE/5ML; EQ 37.5MG HCL/5ML N18050 001 JAN 04, 1984
> DLT > /PENNWALT/ /EQ/4MG/MALEATE/5ML;/ /EQ/37.5MG/HCL/5ML/ /N18050/001/ /JAN/04,/1984/

IBUPROFEN

TABLET; ORAL
IBUPROFEN
MUTUAL PHARM 200MG N72249 001 JAN 10, 1989

OXYMETAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
> ADD > VISINE II
> ADD > PFIZER 0.025% N19407 001 MAR 31, 1989

POVIDONE-IODINE

SOLUTION; TOPICAL
> ADD > POVIDONE IODINE
> ADD > BAXTER 1% N19522 001 MAR 31, 1989

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
> ADD > TRIPROLIDINE AND PSEUDOEPHRINE HCL
> ADD > KV PHARM 120MG;5MG N71798 001 MAR 16, 1989

PSEUDOEPHEDRINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
PSEUDO-12
> ADD > FISONS EQ 60MG HCL/5ML N19401 001 JUN 19, 1987
> DLT > /PENNWALT/ /EQ/60MG/HCL/5ML/ /N19401/001/ /JUN/19,/1987/

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS / CUMULATIVE SUPPLEMENT NUMBER 3 / JAN'89- MAR'89
APPROVED UNDER SECTION 505 OF THE ACT LIST

NO MARCH 1989 APPROVALS

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

SECTION 526 OF THE FEOERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S ORUG, ANTIBIOTIC, OR BIOLOGICAL PROOUCT AS A "OESIGNATEO ORPHAN ORUG". SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW ORUG, ANTIBIOTIC, OR BIOLOGICAL PROOUCT APPROVAL FOR A OESIGNATEO ORPHAN DRUG FOR THE OESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKEO BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINOING THAT THE SPONSOR HOLOING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

ORPHAN DRUG EXCLUSIVE APPROVAL STATUS (CODEO OOE) APPLIES ONLY TO THE APPROVED OR LICENSEO INDICATION(S) FOR WHICH ORPHAN DRUG DESIGNATION HAS BEEN GRANTEO PURSUANT TO SECTION 526 OF THE ACT.

FOR THE FOLLOWING ORUG PRODUCTS WITH ORPHAN DRUG EXCLUSIVE APPROVAL STATUS, THE SPONSOR HAS SEVEN YEARS OF EXCLUSIVE APPROVAL FOR THE APPROVEO INOICATION BEGINNING ON THE DATE OF NDA, ANTIBIOTIC APPLICATION, OR BIOLOGICAL LICENSE APPROVAL FOR THE ORUG. NO SUBSEQUENT SPONSOR MAY RECEIVE APPROVAL OF AN NDA, BIOLOGICAL LICENSE, PAPER NDA, ANTIBIOTIC APPLICATION, ANOA, OR ABBREVIATEO ANTIBIOTIC APPLICATION DURING THE SEVEN YEAR PERIOO FOR THE ORUG ANO INDICATION(S) FOR WHICH OOE STATUS IS MAINTAINEO UNLESS THE EXCLUSIVE APPROVAL HAS BEEN REVOKED AS OESCRIBED ABOVE OR THE SUBSEQUENT SPONSOR HAS OBTAINED WRITTEN CONSENT FROM THE SPONSOR WHO HAS RECEIVEO EXCLUSIVE APPROVAL.

BIOLOGICAL PRODUCTS, ANTIBIOTICS, ANO ORUGS THAT HAVE BEEN APPROVED UNDER SECTION 505 OR 507 OF THE ACT OR UNOER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT FOR MARKETING ANO HAVE BEEN GIVEN ORPHAN DRUG EXCLUSIVE APPROVAL WILL BE NOTEO BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION ADDENDUM. DRUG PROOUCTS THAT HAVE RECEIVEO THE WRITTEN PERMISSION OF THE SPONSOR THAT HAS ORPHAN ORUG EXCLUSIVE APPROVAL TO BE APPROVED UNDER SECTION 527(b)(2) OF THE ACT ARE ALSO NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION AOOENOUM. THESE ORUG PROOUCTS OO NOT HAVE ANY EXCLUSIVE APPROVAL RIGHTS OF THEIR OWN, BUT CAN BE MARKETEO BECAUSE OF THE CONSENT GIVEN BY THE SPONSOR THAT HAS EXCLUSIVE APPROVAL. THESE PRODUCTS ARE MARKEO BY AN (*) NEXT TO THE APPLICANT'S NAME.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF ORPHAN ORUG PROOUCTS WITH EXCLUSIVE APPROVAL OATA. ONLY NEW DATA WILL BE AOOEO TO THE CUMULATIVE SUPPLEMENT.

NO MARCH 1989 APPROVALS

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

NO MARCH 1989 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFN-250, ROOM 17B-06, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
ALBULTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER)	AUG 25, 1988	FEB 09, 1989

ANDA SUITABILITY PETITIONS

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) 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 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN HYDROCODONE BITARTRATE TABLET; ORAL	650MG 10MG	88 P-0416/CP	MORAVEC	NEW STRENGTH	APPROVED MAR 01, 1989
CARMUSTINE, STERILE INJECTABLE; INJECTION	200MG/VIAL	88 P-0410/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (250ML/CONTAINER)	88 P-0379/CP	BAXTER	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989
HALOPERIDOL DECANOATE INJECTABLE; INJECTION	EQ 50MG BASE/ML (2ML/CONTAINER)	88 P-0411/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE IN PLASTIC CONTAINER POWDER FOR RECONSTITUTION; ORAL	59GM/PACKET 0.7425GM/PACKET 1.685GM/PACKET 1.465M/PACKET 5.685GM/PACKET	88P-0419/CP	GUIDELINES	NEW STRENGTH	APPROVED MAR 01, 1989
PREDNISONE CAPSULE; ORAL	1MG 2.5MG 5MG 10MG 20MG 25MG 50MG	88 P-0391/CP	ASCHER	NEW DOSAGE FORM	APPROVED MAR 01, 1989
THIOTEPA, STERILE INJECTABLE; INJECTION	30MG/VIAL 60MG/VIAL	88 P-0412/CP	QUAD PHARMS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH 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-84	ADJUNCTIVE THERAPY TO DIET TO REDUCE THE RISK OF CORONARY ARTERY DISEASE
I-85	SELECTIVE ADULT VISCERAL ARTERIOGRAPHY
I-86	METASTATIC BREAST CANCER IN PREMENOPAUSAL WOMEN AS AN ALTERNATIVE TO OOPHORECTOMY OR OVARIAN IRRADIATION

PATENT USE CODE

U-41	METHOD FOR TREATING PROSTATIC CARCINOMA COMPRISING ADMINISTERING FLUTAMIDE
U-42	METHOD FOR TREATING PROSTATE ADENOCARCINOMA COMPRISING ADMINISTERING AN ANTIANDROGEN INCLUDING FLUTAMIDE AND AN LHRH AGONIST
U-43	REDUCING CHOLESTEROL IN CHOLELITHIASIS PATIENTS
U-44	REDUCING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-45	DISSOLVING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-46	CEREBRAL, CORONARY, PERIPHERAL, VISCERAL AND RENAL ARTERIOGRAPHY, AORTOGRAPHY AND LEFT VENTRICULOGRAPHY
U-47	CT IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY
U-48	CEREBRAL ANGIOGRAPHY, AND VENOGRAPHY
U-49	INTRA-ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
U-50	PALLIATIVE TREATMENT OF PATIENTS WITH OVARIAN CARCINOMA RECURRENT AFTER PRIOR CHEMOTHERAPY, INCLUDING PATIENTS WHO HAVE BEEN PREVIOUSLY TREATED WITH CISPLATIN

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19880 001	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
>ADD>	19880 002	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
>ADD>	19880 003	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19471 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	18554 001	FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993		NCE	JAN 27, 1994
			4472382	SEP 18, 2001	U-42		
			4329364	MAY 11, 1999	U-41		
	18422 001	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	18422 002	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	18422 003	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	19778 001	HYDROCHLOROTHIAZIDE; PRINZIDE 12.5	4472380	SEP 18, 2001		NCE	DEC 29, 1992
			4374829	DEC 30, 2001		NC	FEB 16, 1992
	19778 002	HYDROCHLORDTHIAZIDE; PRINZIDE 25	4472380	SEP 18, 2001		NCE	DEC 29, 1992
			4374829	DEC 30, 2001		NC	FEB 16, 1992
>ADD>	18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-85	MAR 31, 1992
>ADD>	18956 004	IOHEXOL; OMNIPAQUE 350	4021481	MAY 03, 1994		I-85	MAR 31, 1992
>ADD>	19710 001	IOVERSOL; OPTIRAY-320	4396598	AUG 02, 2000	U-46	NCE	DEC 30, 1993
>ADD>			4396598	AUG 02, 2000	U-47		
>ADD>	19710 002	IOVERSOL; OPTIRAY-240	4396598	AUG 02, 2000	U-48	NCE	DEC 30, 1993
>ADD>	19710 003	IOVERSOL; OPTIRAY-160	4396598	AUG 02, 2000	U-49	NCE	DEC 30, 1993
	19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NCE	APR 09, 1990
						NP	JAN 26, 1992
	19625 001	MOMETASONE FUROATE; ELOCON	4808610	FEB 28, 2006			
>ADD>	19796 001	MOMETASONE FUROATE; ELOCON	4775529	OCT 04, 2005		NCE	APR 30, 1992
>ADD>			4472393	SEP 18, 2001		NDF	MAR 30, 1992
	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
	19508 001	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
	19508 002	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
>ADD>	19407 001	OXYMETAZOLINE HYDROCHLORIDE; VISINE II				NDF	MAY 30, 1989
	18737 001	SULCONAZOLE NITRATE; SULCOSYN	4055652	OCT 25, 1996		NCE	AUG 30, 1990
						NDF	FEB 28, 1992

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	17970 001	TAMOXIFEN CITRATE; NOLVADEX				I-86	MAR 16, 1992
>ADD>	19829 001	TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC	4789736	DEC 06, 2005			
	19594 001	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
			RE30910	JAN 07, 1994	U-44		
			RE30910	JAN 07, 1994	U-45		
	19594 002	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
			RE30910	JAN 07, 1994	U-44		
			RE30910	JAN 07, 1994	U-45		