CUMULATIVE SUPPLEMENT 1

JAN'92

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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

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THERAPEUTIC EQUIVALENCE EVALUATIONS

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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 12th 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 Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 Division of Blood and Blood Products lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. 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. A newly approved product is also identified by a lozenge (◆) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck 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 12th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 13th 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

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; or when an applicant name is changed to meet internal publication standards. Therefore, 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 (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREIVATED NAME)
RECKITT AND COLMAN PHARMACEUTICALS INC (R & C)	RECKITT AND COLMAN PHARMACEUTICALS INC (RECKITT AND COLMAN)

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 1991) 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 1991	MAR 1992	JUN 1992	SEP 1992
DRUG PRODUCTS LISTED	9258			
SINGLE SOURCE	2187 (22.8%)			
MULTISOURCE	7397 (77.2%)			
THERAPEUTICALLY EQUIVALENT	6580 (68.7%)			
NOT THERAPEUTICALLY EQUIVALENT	664 (6.9%)			
EXCEPTIONS[1]	153 (1.6%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	430			

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

IX

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

		ACETAMINOPHEN W/ CODEINE PHOSPHATE		
>DLT >	/AA/	/CHELSEA/	/300MG;15MG/	/N87277/001/ /MAY/26/1982/
>DLT >				
>DLT >	/AA/		/300MG;30MG/	/N87276/001/ /MAY/26/1982/
>DLT >				
>DLT >	/AA/		/300MG;60MG/	/N87275/001/ /MAY/26/1982/
>DLT >				
>ADD >		∂ CHELSEA	300MG;15MG	N87277 001 MAY 26, 1982
>ADD >				
>ADD >		∂	300MG;30MG	N87276 001 MAY 26, 1982
>ADD >				
>ADD >		∂	300MG;60MG	N87275 001 MAY 26, 1982
>ADD >				

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

		HYDROCODONE BITARTRATE AND ACETAMINOPHEN		
>ADD >	AA	MIKART	500MG;5MG	N89697 001 JAN 28, 1992
>ADD >				
>DLT >	/B*/	/PHARM/BASICS/	/500MG;5MG/	/N89291/001/ /MAY/29/1987/
>DLT >				
>ADD >		∂ PHARM BASICS	500MG;5MG	N89291 001 MAY 29, 1987
>ADD >				

ACETOHEXAMIDE

TABLET; ORAL

		ACETOHEXAMIDE		
>DLT >	/B*/	/PHARM/BASICS/	/250MG/	/N70753/001/ /NOV/03/1986/
>DLT >				
>DLT >	/B*/		/500MG/	/N70754/001/ /NOV/03/1986/
>DLT >				
>ADD >		∂ PHARM BASICS	250MG	N70753 001 NOV 03, 1986
>ADD >				
>ADD >		∂	500MG	N70754 001 NOV 03, 1986
>ADD >				

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

		CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL		
>DLT >	/B*/	/PHARM/BASICS/	/EQ 12.5MG BASE;5MG/	/N70477/001/ /JAN/12/1988/
>DLT >				
>DLT >	/B*/		/EQ 25MG BASE;10MG/	/N70478/001/ /JAN/12/1988/
>DLT >				
>ADD >		∂ PHARM BASICS	EQ 12.5MG BASE;5MG	N70477 001 JAN 12, 1988
>ADD >				
>ADD >		∂	EQ 25MG BASE;10MG	N70478 001 JAN 12, 1988
>ADD >				

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

		PERPHENAZINE AND AMITRIPTYLINE HCL		
>DLT >		/S/CHELSEA/	/50MG;4MG/	/N71556/001/ /MAR/02/1987/
>DLT >				

AMOXICILLIN

CAPSULE; ORAL

		/UTIMOX/		
>DLT >				
>DLT >	/AA/	/PARKE/DAVIS/	/250MG/	/N62107/001/
>DLT >	/AA/		/500MG/	/N62107/002/
>ADD >		∂ PARKE DAVIS	250MG	N62107 001
>ADD >		∂	500MG	N62107 002

POWDER FOR RECONSTITUTION; ORAL

		/UTIMOX/		
>DLT >				
>DLT >	/AA/	/PARKE/DAVIS/	/125MG/5ML/	/N62127/001/
>DLT >	/AA/		/250MG/5ML/	/N62127/002/
>ADD >		∂ PARKE DAVIS	125MG/5ML	N62127 001
>ADD >		∂	250MG/5ML	N62127 002

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

		/AMCILL/		
>DLT >				
>DLT >	/AA/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62041/001/
>DLT >	/AA/		/EQ 500MG BASE/	/N62041/002/
>ADD >		∂ PARKE DAVIS	EQ 250MG BASE	N62041 001
>ADD >		∂	EQ 500MG BASE	N62041 002

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

> DLT >		/AMCILL/			
> DLT >	/AA/	/PARKE/DAVIS/	/EQ 125MG BASE/5ML/	/N62030/001/	
> DLT >	/AA/		/EQ 250MG BASE/5ML/	/N62030/002/	
> ADD >		ə PARKE DAVIS	EQ 125MG BASE/5ML	N62030 001	
> ADD >		ə	EQ 250MG BASE/5ML	N62030 002	

ATENOLOL

TABLET; ORAL

ATENOLOL

> ADD >	AB	MYLAN	50MG	N73456 001	
> ADD >				JAN 24, 1992	
> ADD >	AB		100MG	N73457 001	
> ADD >				JAN 24, 1992	

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

> DLT >	/AA/	/CHELSEA/	/0.025MG;2.5MG/	/N85876/001/	
> ADD >		ə CHELSEA	0.025MG;2.5MG	N85876 001	

BACLOFEN

TABLET; ORAL

BACLOFEN

> DLT >	/B*/	/PHARM/BASICS/	/10MG/	/N71260/001/	
> DLT >				/MAY/06,/1988/	
> DLT >	/B*/		/20MG/	/N71261/001/	
> DLT >				/MAY/06,/1988/	
> ADD >		ə PHARM BASICS	10MG	N71260 001	
> ADD >				MAY 06, 1988	
> ADD >		ə	20MG	N71261 001	
> ADD >				MAY 06, 1988	

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

> ADD >	AA	MUTUAL PHARM	1MG	N81264 001	
> ADD >				JAN 23, 1992	
> ADD >	AA		2MG	N81265 001	
> ADD >				JAN 23, 1992	

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

> DLT >	/B*/	/PHARM/BASICS/	/0.5MG/	/N89211/001	
> DLT >				/JUN/14,/1988	
> DLT >	/B*/		/1MG/	/N89212/001	
> DLT >				/JUN/14,/1988	
> DLT >	/B*/		/2MG/	/N89213/001	
> DLT >				/JUN/14,/1988	
> ADD >		ə PHARM BASICS	0.5MG	N89211 001	
> ADD >				JUN 14, 1988	
> ADD >		ə	1MG	N89212 001	
> ADD >				JUN 14, 1988	
> ADD >		ə	2MG	N89213 001	
> ADD >				JUN 14, 1988	

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

> DLT >	/B*/	/PHARM/BASICS/	/200MG/	/N70300/001	
> DLT >				/MAY/15,/1986	
> ADD >		ə PHARM BASICS	200MG	N70300 001	
> ADD >				MAY 15, 1986	

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

> DLT >	/AA/	/VITARINE/	/350MG/	/N89566/001	
> DLT >				/AUG/30,/1988	
> ADD >	B*	VITARINE	350MG	N89566 001	
> ADD >				AUG 30, 1988	

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

> DLT >	/AA/	/PARKE/DAVIS/	/5MG/	/N85163/001	
> DLT >	/AB/		/10MG/	/N84598/001	
> DLT >	/AB/		/25MG/	/N85164/001	
> ADD >		ə PARKE DAVIS	5MG	N85163 001	
> ADD >		ə	10MG	N84598 001	
> ADD >		ə	25MG	N85164 001	

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

>DLT >	/B*/	/PHARM/BASICS/	/100MG/	/N88708/001/ /AUG/30,/1984/
>DLT >				
>DLT >	/B*/		/250MG/	/N88709/001/ /AUG/30,/1984/
>DLT >				
>ADD >		∂ PHARM BASICS	100MG	N88708 001 AUG 30, 1984
>ADD >				
>ADD >		∂	250MG	N88709 001 AUG 30, 1984
>ADD >				

CLEMASTINE FUMARATE

TABLET; ORAL
CLEMASTINE FUMARATE

>ADD >	AB	LEMMON	1.34MG‡	N73282 001 JAN 31, 1992
>ADD >				
>ADD >	AB		2.68MG‡	N73283 001 JAN 31, 1992
>ADD >				
		TAVIST		
>ADD >	AB	+ DORSEY	2.68MG	N17661 001
		TAVIST-1		
>ADD >	AB	DORSEY	1.34MG	N17661 002

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

>DLT >	/B*/	/PHARM/BASICS/	/3.75MG/	/N71242/001/ /MAY/20,/1987/
>DLT >				
>DLT >	/B*/		/7.5MG/	/N71243/001/ /MAY/20,/1987/
>DLT >				
>DLT >	/B*/		/15MG/	/N71244/001/ /MAY/20,/1987/
>DLT >				
>ADD >		∂ PHARM BASICS	3.75MG	N71242 001 MAY 20, 1987
>ADD >				
>ADD >		∂	7.5MG	N71243 001 MAY 20, 1987
>ADD >				
>ADD >		∂	15MG	N71244 001 MAY 20, 1987
>ADD >				

COLCHICINE; PROBENECID

TABLET; ORAL
/PROBEN-C/

>DLT >	/BP/	/CHELSEA/	/0.5MG;500MG/	/N85552/001/
>ADD >		∂ CHELSEA	0.5MG;500MG	N85552 001

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

>DLT >	/B*/	/PHARM/BASICS/	/25MG/	/N71864/001/ /SEP/09,/1987/
>DLT >				
>DLT >	/B*/		/50MG/	/N71865/001/ /SEP/09,/1987/
>DLT >				
>DLT >	/B*/		/75MG/	/N71866/001/ /SEP/09,/1987/
>DLT >				
>DLT >	/B*/		/100MG/	/N71867/001/ /SEP/09,/1987/
>DLT >				
>ADD >		∂ PHARM BASICS	25MG	N71864 001 SEP 09, 1987
>ADD >				
>ADD >		∂	50MG	N71865 001 SEP 09, 1987
>ADD >				
>ADD >		∂	75MG	N71866 001 SEP 09, 1987
>ADD >				
>ADD >		∂	100MG	N71867 001 SEP 09, 1987
>ADD >				

DESONIDE

LOTION; TOPICAL
DESOWEN

>ADD >		OWEN GALDERMA	0.05%‡	N72354 001 JAN 24, 1992
>ADD >				

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE

>DLT >	/B*/	/CHELSEA/	/EQ/100MG/BASE/	/N71020/001/ /DEC/01,/1986/
>DLT >				
>DLT >	/B*/		/EQ/150MG/BASE/	/N71021/001/ /DEC/01,/1986/
>DLT >				

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION
DOPRAM

>ADD >	AP	ROBINS	20MG/ML	N14879 001
>ADD >		DOXAPRAM HCL		
>ADD >	AP	STERIS	20MG/ML‡	N73529 001 JAN 30, 1992
>ADD >				

DROPERIDOL

INJECTABLE; INJECTION

		DROPERIDOL		
> DLT >	/AP/	/SOLOPAK/	/2.5MG/ML/	/N71750/001/ /SEP/06,/1988/
> DLT >				
> ADD >		∂ SOLOPAK	2.5MG/ML	N71750 001 SEP 06, 1988
> ADD >				

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

		FLURAZEPAM HCL		
> DLT >	/B*/	/PHARM/BASICS/	/15MG/	/N70562/001/ /JUL/09,/1987/
> DLT >				
> DLT >	/B*/		/30MG/	/N70563/001/ /JUL/09,/1987/
> DLT >				
> ADD >		∂ PHARM BASICS	15MG	N70562 001 JUL 09, 1987
> ADD >				
> ADD >		∂	30MG	N70563 001 JUL 09, 1987
> ADD >				

HYDROCHLOROTHIAZIDE

TABLET; ORAL

		HYDROCHLOROTHIAZIDE		
> ADD >	AB	DANBURY	25MG¤	N81189 001 JAN 24, 1992
> ADD >				
> ADD >	AB		100MG¤	N81190 001 JAN 24, 1992
> ADD >				

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL

> DLT >		/HYDROFLUMETHIAZIDE/AND/RESERPINE/		
> DLT >	/B*/	/PHARM/BASICS/	/50MG;0.125MG/	/N88195/001/ /OCT/26,/1983/
> DLT >				
> ADD >		∂ PHARM BASICS	50MG;0.125MG	N88195 001 OCT 26, 1983
> ADD >				

> ADD > HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

> ADD >		PAREMYD		
> ADD >		ALLERGAN	1%;0.25%¤	N19261 001 JAN 30, 1992
> ADD >				

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

		HYDROXYZINE HCL		
> DLT >	/B*/	/PHARM/BASICS/	/10MG/	/N89121/001/ /MAR/20,/1986/
> DLT >				
> DLT >	/B*/		/25MG/	/N89122/001/ /MAR/20,/1986/
> DLT >				
> DLT >	/B*/		/50MG/	/N89123/001/ /MAR/20,/1986/
> DLT >				
> ADD >		∂ PHARM BASICS	10MG	N89121 001 MAR 20, 1986
> ADD >				
> ADD >		∂	25MG	N89122 001 MAR 20, 1986
> ADD >				
> ADD >		∂	50MG	N89123 001 MAR 20, 1986
> ADD >				

IOVERSOL

INJECTABLE; INJECTION

> ADD >		OPTIRAY 300		
> ADD >		MALLINCKRODT	64%¤	N19710 004 JAN 22, 1992
> ADD >				
> ADO >		OPTIRAY 350		
> ADD >		MALLINCKRODT	74%¤	N19710 005 JAN 22, 1992
> ADD >				

LITHIUM CARBONATE

CAPSULE; ORAL

		LITHIUM CARBONATE		
> DLT >	/B*/	/PHARM/BASICS/	/300MG/	/N72542/001/ /FEB/01,/1989/
> DLT >				
> ADD >		∂ PHARM BASICS	300MG	N72542 001 FEB 01, 1989
> ADD >				

LORAZEPAM

TABLET; ORAL

		LORAZEPAM		
> DLT >	/B*/	/PHARM/BASICS/	/1MG/	/N70539/001/ /DEC/22,/1986/
> DLT >				
> DLT >	/B*/		/2MG/	/N70540/001/ /DEC/22,/1986/
> DLT >				
> ADD >		∂ PHARM BASICS	1MG	N70539 001 DEC 22, 1986
> ADD >				
> ADD >		∂	2MG	N70540 001 DEC 22, 1986
> ADD >				

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM

>DLT>	/B*/ /PHARM/BASICS/	/EQ/50MG/BASE/	/N71007/001/ /MAR/25,/1988/	
>DLT>	/B*/	/EQ/100MG/BASE/	/N71008/001/ /MAR/25,/1988/	
>ADD>	∂ PHARM BASICS	EQ 50MG BASE	N71007 001 MAR 25, 1988	
>ADD>	∂	EQ 100MG BASE	N71008 001 MAR 25, 1988	

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE

>DLT>	/B*/ /PHARM/BASICS/	/20MG/	/N70646/001/ /OCT/02,/1987/	
>DLT>	/B*/	/40MG/	/N70647/001/ /OCT/02,/1987/	
>ADD>	∂ PHARM BASICS	20MG	N70646 001 OCT 02, 1987	
>ADD>	∂	40MG	N70647 001 OCT 02, 1987	

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL

>DLT>	/BE/ /PARKE/DAVIS/	/50MG/ML/	/N80364/002/	
>DLT>	/BE/	/100MG/ML/	/N80364/001/	
>ADD>	∂ PARKE DAVIS	50MG/ML	N80364 002	
>ADD>	∂	100MG/ML	N80364 001	

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE

>DLT>	/AA/ /PARKE/DAVIS/	/200MG/	/N84744/001/	
>DLT>	/AA/	/400MG/	/N84744/002/	
>ADD>	∂ PARKE DAVIS	200MG	N84744 001	
>ADD>	∂	400MG	N84744 002	

MESALAMINE

TABLET, DELAYED RELEASE; ORAL
ASACOL

>ADD>	+ NORWICH EATON	400MG✠	N19651 001 JAN 31, 1992

METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE

>DLT>	/B*/ /PHARM/BASICS/	/10MG/	/N71013/001/ /JAN/25,/1988/	
>DLT>	/B*/	/20MG/	/N71014/001/ /JAN/25,/1988/	
>ADD>	∂ PHARM BASICS	10MG	N71013 001 JAN 25, 1988	
>ADD>	∂	20MG	N71014 001 JAN 25, 1988	

METHYCLOTHIAZIDE

TABLET; ORAL
METHYCLOTHIAZIDE

>DLT>	/B*/ /PHARM/BASICS/	/5MG/	/N88745/001/ /MAR/21,/1985/	
>ADD>	∂ PHARM BASICS	5MG	N88745 001 MAR 21, 1985	

METOCLOPRAMIDE HYDROCHLORIDE

CONCENTRATE; ORAL
METOCLOPRAMIDE INTENSOL

>ADD>	ROXANE	EQ 10MG BASE/ML✠	N72995 001 JAN 30, 1992

TABLET; ORAL
METOCLOPRAMIDE HCL

>DLT>	/B*/ /PHARM/BASICS/	/EQ/10MG/BASE/	/N70339/001/ /JUL/29,/1985/	
>ADD>	∂ PHARM BASICS	EQ 10MG BASE	N70339 001 JUL 29, 1985	

> ADD > METOPROLOL SUCCINATE

> ADD > TABLET, EXTENDED RELEASE; ORAL
> ADD > TOPROL XL
> ADD > + HASSLE EQ 50MG TARTRATE N19962 001 JAN 10, 1992
> ADD > + EQ 100MG TARTRATE N19962 002 JAN 10, 1992
> ADD > + EQ 200MG TARTRATE N19962 003 JAN 10, 1992

MINOXIDIL

TABLET; ORAL
MINOXIDIL
> DLT > /B*/ /PHARM/BASICS/ /2.5MG/ /N71537/001/ /DEC/16,/1988/
> DLT >
> ADD > ∂ PHARM BASICS 2.5MG N71537 001 DEC 16, 1988
> ADD >

> ADD > MIVACURIUM CHLORIDE

> ADD > INJECTABLE; INJECTION
> ADD > MIVACRON
> ADD > BURROUGHS WELLCOME EQ 2MG BASE/ML N20098 001 JAN 22, 1992
> ADD >
> ADD > MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER
> ADD > BURROUGHS WELLCOME EQ 0.5MG BASE/ML N20098 002 JAN 22, 1992
> ADD >
> ADD > EQ 50MG BASE/100ML N20098 003 JAN 22, 1992
> ADD >

NICARDIPINE HYDROCHLORIDE

> ADD > INJECTABLE; INJECTION
> ADD > CARDENE
> ADD > DUPONT MERCK 2.5MG/ML N19734 001 JAN 30, 1992
> ADD >

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
> ADD > PROSTEP
> ADD > + ELAN 11MG/24HR N19983 001 JAN 28, 1992
> ADD >
> ADD > + 22MG/24HR N19983 002 JAN 28, 1992
> ADD >

NYSTATIN

TABLET; ORAL
NYSTATIN
> DLT >/AA/ /CHELSEA/ /500,000 UNITS/ /N62402/001/ /DEC/16,/1982/
> DLT >
> ADD > ∂ CHELSEA 500,000 UNITS N62402 001 DEC 16, 1982
> ADD >

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM
> DLT > /B*/ /CHELSEA/ /10MG/ /N71661/001/ /MAR/02,/1988/
> DLT >
> DLT > /B*/ /15MG/ /N71662/001/ /MAR/02,/1988/
> DLT >
> DLT > /B*/ /30MG/ /N71663/001/ /MAR/02,/1988/
> DLT >

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYNIN CHLORIDE
> DLT > /B*/ /PHARM/BASICS/ /5MG/ /N70746/001/ /MAR/10,/1988/
> DLT >
> ADD > ∂ PHARM BASICS 5MG N70746 001 MAR 10, 1988
> ADD >

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM
> DLT >/AP/ /PARKE/DAVIS/ /1,000,000 UNITS/VIAL/ /N62003/001/
> DLT >/AP/ /5,000,000 UNITS/VIAL/ /N62003/002/
> ADD > ∂ PARKE DAVIS 1,000,000 UNITS/VIAL N62003 001
> ADD > ∂ 5,000,000 UNITS/VIAL N62003 002

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
> DLT > /PENAPAR-VK/
> DLT >/AA/ /PARKE/DAVIS/ /EQ 125MG BASE/5ML/ /N62002/001/
> DLT >/AA/ /EQ 250MG BASE/5ML/ /N62002/002/
> ADD > ∂ PARKE DAVIS EQ 125MG BASE/5ML N62002 001
> ADD > ∂ EQ 250MG BASE/5ML N62002 002

PENICILLIN V POTASSIUM

TABLET; ORAL

>DLT >	/PENAPAR-VK/			
>DLT >/AB/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62001/001/	
>DLT >/AB/		/EQ 500MG BASE/	/N62001/002/	
>ADD >	∂ PARKE DAVIS	EQ 250MG BASE	N62001 001	
>ADD >	∂	EQ 500MG BASE	N62001 002	

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

>DLT > /B*/	/CHELSEA/	/8MG/	/N89166/001/	
>DLT >			/DEC/23,/1987/	

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL

>DLT >	/PHENYTOIN/SODIUM/			
>DLT > /BX/	/CHELSEA/	/100MG/	/N85894/001/	
>ADD >	∂ CHELSEA	100MG	N85894 001	

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

POWDER FOR RECONSTITUTION; ORAL

>ADD >	CO-LAV			
>ADD > AA	COPLEY	240GM/BOT;2.98GM/BOT;6.72GM/BOT;		
>ADD >		5.84GM/BOT;22.72GM/BOT‡	N73428 001	
>ADD >			JAN 28, 1992	

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	K-LEASE			
>ADD > AB	ADRIA	8MEQ‡	N73398 001	
>ADD >			JAN 28, 1992	
	MICRO-K			
>ADD > AB	ROBINS	8MEQ	N18238 001	

PRAZEPAM

CAPSULE; ORAL

CENTRAX

>DLT >/AB/	/PARKE/DAVIS/	/5MG/	/N18144/001/	
>DLT >/AB/		/10MG/	/N18144/002/	
>ADD >	+ PARKE DAVIS	10MG	N18144 002	
>ADD >		5MG	N18144 001	

>DLT >	/PRAZEPAM/			
>DLT > /B*/	/PHARM/BASICS/	/5MG/	/N70427/001/	
>DLT >			/NOV/06,/1987/	
>DLT > /B*/		/10MG/	/N70428/001/	
>DLT >			/NOV/06,/1987/	
>ADD >	∂ PHARM BASICS	5MG	N70427 001	
>ADD >			NOV 06, 1987	
>ADD >	∂	10MG	N70428 001	
>ADD >			NOV 06, 1987	

PRAZOSIN HYDROCHLORIDE

>ADD >	TABLET, EXTENDED RELEASE; ORAL		
>ADD >	MINIPRESS XL		
>ADD >	+ PFIZER	2.5MG‡	N19775 001
>ADD >			JAN 29, 1992
>ADD >	+	5MG‡	N19775 002
>ADD >			JAN 29, 1992

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

>DLT > /B*/	/PHARM/BASICS/	/400MG;80MG/	/N70203/001/	
>DLT >			/NOV/08,/1985/	
>DLT > /B*/		/800MG;160MG/	/N70204/001/	
>DLT >			/NOV/08,/1985/	
>ADD >	∂ PHARM BASICS	400MG;80MG	N70203 001	
>ADD >			NOV 08, 1985	
>ADD >	∂	800MG;160MG	N70204 001	
>ADD >			NOV 08, 1985	

SULFISOXAZOLE

TABLET; ORAL

>DLT >	/SULFALAR/			
>DLT >/AB/	/PARKE/DAVIS/	/500MG/	/N84955/001/	
>ADD >	∂ PARKE DAVIS	500MG	N84955 001	

> ADD > TEMAFLOXACIN HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > OMNIFLOX
> ADD > + ABBOTT — EQ 600MG BASE* — N20043 004 JAN 30, 1992
> ADD > — EQ 400MG BASE* — N20043 003 JAN 30, 1992
> ADD >

TEMAZEPAM

CAPSULE; ORAL
TEMAZEPAM

> DLT > /B*/	/PHARM/BASICS/	/15MG/	/N70489/001/ /JUL/07,/1986/
> DLT >			
> DLT > /B*/		/30MG/	/N70490/001/ /JUL/07,/1986/
> DLT >			
> ADD >	a PHARM BASICS	15MG	N70489 001 JUL 07, 1986
> ADD >			
> ADD >	a	30MG	N70490 001 JUL 07, 1986
> ADD >			

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
THIAMINE HCL

> DLT >/B*/	/PARKE/DAVIS/	/100MG/ML/	/N80770/001/
> ADD >	a PARKE DAVIS	100MG/ML	N80770 001

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

> DLT > /B*/	/PHARM/BASICS/	/5MG/	/N72001/001/ /JAN/10,/1989/
> DLT >			
> DLT > /B*/		/10MG/	/N72002/001/ /JAN/10,/1989/
> DLT >			
> DLT > /B*/		/20MG/	/N72003/001/ /JAN/10,/1989/
> DLT >			
> ADD >	a PHARM BASICS	5MG	N72001 001 JAN 10, 1989
> ADD >			
> ADD >	a	10MG	N72002 001 JAN 10, 1989
> ADD >			
> ADD >	a	20MG	N72003 001 JAN 10, 1989
> ADD >			

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

> ADD > AP	GENSIA	EQ 40MG BASE/ML*	N63100 001 JAN 30, 1992
> ADD >			

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

> DLT > /B*/	/PHARM/BASICS/	/100MG/	/N71355/001/ /JAN/11,/1988/
> DLT >			
> DLT > /B*/		/250MG/	/N70168/001/ /APR/02,/1986/
> DLT >			
> DLT > /B*/		/500MG/	/N70169/001/ /APR/02,/1986/
> DLT >			
> ADD >	a PHARM BASICS	100MG	N71355 001 JAN 11, 1988
> ADD >			
> ADD >	a	250MG	N70168 001 APR 02, 1986
> ADD >			
> ADD >	a	500MG	N70169 001 APR 02, 1986
> ADD >			

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

> DLT >/B*/	/PARKE/DAVIS/	/500MG/	/N86047/001/
> ADD >	a PARKE DAVIS	500MG	N86047 001

TOLMETIN SODIUM

CAPSULE; ORAL
TOLMETIN SODIUM

> ADD > AB	BAKER CUMMINS	EQ 400MG BASE*	N73392 001 JAN 24, 1992
> ADD >			
> ADD > AB	PUREPAC	EQ 400MG BASE*	N73308 001 JAN 24, 1992
> ADD >			

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

> DLT >	/B*/ /PHARM/BASICS/	/50MG/	/N70491/001/	
> DLT >			/APR/29,/1987/	
> DLT >	/B*/	/100MG/	/N70492/001/	
> DLT >			/APR/29,/1987/	
> ADD >	∂ PHARM BASICS	50MG	N70491 001	
> ADD >			APR 29, 1987	
> ADD >	∂	100MG	N70492 001	
> ADD >			APR 29, 1987	

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
SURMONTIL

> DLT >	/AB/ /WYETH/AYERST/	/EQ 25MG BASE/	/N16792/001/	
> DLT >	/AB/	/EQ 50MG BASE/	/N16792/002/	
> DLT >	/AB//+/	/EQ 100MG BASE/	/N16792/003/	
> DLT >			/SEP/15,/1982/	
> ADD >	+ WYETH AYERST	EQ 100MG BASE	N16792 003	
> ADD >			SEP 15, 1982	
> ADD >		EQ 25MG BASE	N16792 001	
> ADD >		EQ 50MG BASE	N16792 002	
> DLT >	/TRIMIPRAMINE/MALEATE/			
> DLT >	/B*/ /PHARM/BASICS/	/EQ/25MG/BASE/	/N71283/001/	
> DLT >			/DEC/08,/1987/	
> DLT >	/B*/	/EQ/50MG/BASE/	/N71284/001/	
> DLT >			/DEC/08,/1987/	
> DLT >	/B*/	/EQ/100MG/BASE/	/N71285/001/	
> DLT >			/DEC/08,/1987/	
> ADD >	∂ PHARM BASICS	EQ 25MG BASE	N71283 001	
> ADD >			DEC 08, 1987	
> ADD >	∂	EQ 50MG BASE	N71284 001	
> ADD >			DEC 08, 1987	
> ADD >	∂	EQ 100MG BASE	N71285 001	
> ADD >			DEC 08, 1987	

VECURONIUM BROMIDE

INJECTABLE; INJECTION
NORCURON

> ADD >	ORGANON	20MG/VIAL¤	N18776 003
> ADD >			JAN 03, 1992

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
VERELAN

> ADD >	+ ELAN	180MG¤	N19614 003
> ADD >			JAN 09, 1992

TABLET; ORAL
VERAPAMIL HCL

> DLT >	/B*/ /CHELSEA/	/80MG/	/N70421/001/	
> DLT >			/SEP/17,/1986/	
> DLT >	/B*/	/120MG/	/N70422/001/	
> DLT >			/SEP/17,/1986/	

WARFARIN SODIUM

TABLET; ORAL
/WARFARIN/SODIUM/

> DLT >	/B*/ /PHARM/BASICS/	/2MG/	/N88719/001/	
> DLT >			/JUN/27,/1985/	
> DLT >	/B*/	/2.5MG/	/N88720/001/	
> DLT >			/AUG/06,/1985/	
> DLT >	/B*/	/5MG/	/N88721/001/	
> DLT >			/JUL/02,/1985/	
> ADD >	∂ PHARM BASICS	2MG	N88719 001	
> ADD >			JUN 27, 1985	
> ADD >	∂	2.5MG	N88720 001	
> ADD >			AUG 06, 1985	
> ADD >	∂	5MG	N88721 001	
> ADD >			JUL 02, 1985	

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL

> ADD >	MICROCC',			
> ADD >	JOHNSON AND JOHNSON	0.5%⊠		N72292 001
> ADD >				JAN 28, 1992

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL

> ADD >	LOPERAMIDE HCL			
> ADD >	PERRIGO	1MG/5ML⊠		N73243 001
> ADD >				JAN 21, 1992

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 1 / JAN '92 - JAN '92

NO JANUARY 1992 APPROVALS

ORPHAN DRUG PRODUCT DESIGNATIONS

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

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ANANAIN, COMOSAIN TRADE: VIANAIN	FOR THE ENZYMATIC DEBRIDEMENT OF SEVERE BURNS.	GENZYME CORPORATION
GENERIC: ANTITHROMBIN III TRADE: THROMBATE III*/**	USE AS REPLACEMENT THERAPY IN CONGENITAL DEFICIENCY OF ANTITHROMBIN-III FOR PREVENTION AND TREATMENT OF OF THROMBOSIS AND PULMONARY EMBOLI. [DEC 13, 1996]	CUTTER BIOLOGICAL
GENERIC: BOTULINUM TOXIN TYPE B TRADE: NOT ESTABLISHED	TREATMENT OF CERVICAL DYSTONIA.	ATHENA NEUROSCIENCES, INC
GENERIC: CILIARY NEUROTROPHIC FACTOR TRADE: NOT ESTABLISHED	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	ROGENERON PHARMACEUTICALS, INC
GENERIC: CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR TRADE: NOT ESTABLISHED	FOR CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR PROTEIN REPLACEMENT THERAPY IN CYSTIC FIBROSIS PATIENTS.	GENZYME CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.*/** [DEC 31, 1998] TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA.*/** [MAR 05, 1998]	IMMUNEX

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: DAPSONE TRADE: DAPSONE	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: L-BACLOFEN TRADE: NEURALGON	TREATMENT OF INTRACTABLE SPASTICITY IN CHILDREN WITH CEREBRAL PALSY.	MERICON INDUSTRIES, INC
GENERIC: LIOTHYRONINE SODIUM TRADE: TRIOSTAT*/**	TREATMENT OF MYXEDEMA COMA/PRE-COMA. [DEC 31, 1998]	SMITHKLINE BEECHAM

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

NO JANUARY 1992 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, HFD-650, MPN-2 ROOM 278, 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, 12TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO JANUARY 1992 ADDITIONS

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, 12TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO JANUARY 1992 PETITIONS APPROVED OR DENIED

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, 12TH 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-57 TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER

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>	20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
>ADD>			4894240	JAN 16, 2007		NP	DEC 27, 1994
>ADD>	20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
>ADD>			4894240	JAN 16, 2007		NP	DEC 27, 1994
>ADD>	20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
>ADD>			4894240	JAN 16, 2007		NP	DEC 27, 1994
>ADD>	20068 001	FOSCARNET SODIUM; FOSCAVIR	4771041	JUL 29, 1997			
>ADD>			4665062	JUL 29, 1997			
>ADD>			4339445	JUL 29, 1997			
>ADD>			4215113	JUL 29, 1997		NCE	SEP 27, 1996
>ADD>	19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
>ADD>	19968 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
>ADD>	19261 001	HYDROXYAMPHETAMINE HYDROBROMIDE; PAREMYD				NC	JAN 30, 1995
>ADD>	19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	NDF	DEC 20, 1994
>ADD>						NCE	NOV 30, 1994
>ADD>	20105 001	LIOTHYRONINE SODIUM; TRIOSTAT				ODE	DEC 31, 1998
>ADD>	19651 001	MESALAMINE; ASACOL				NCE	DEC 24, 1992
>ADD>						NDF	JAN 31, 1995
>ADD>	17659 001	METAPROTERENOL SULFATE; ALUPENT				I-57	NOV 14, 1994
>ADD>	19962 001	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992			
>ADD>			3876802	APR 08, 1992			
>ADD>	20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	AUG 02, 2005		NCE	JAN 22, 1997
>ADD>	20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	AUG 02, 2005		NCE	JAN 22, 1997
>ADD>	19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
>ADD>	19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
>ADD>	19734 001	NICARDIPINE HYDROCHLORIDE; CARDENE				NDF	JAN 30, 1995
>ADD>						NCE	DEC 21, 1993
>ADD>	19983 001	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
>ADD>	19983 002	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
>ADD>	20076 001	NICOTINE; HABITROL	5016652	MAY 21, 2008			
>ADD>	20076 002	NICOTINE; HABITROL	5016652	MAY 21, 2008			
>ADD>	20076 003	NICOTINE; HABITROL	5016652	MAY 21, 2008			
>ADD>	20165 001	NICOTINE; NICODERM	5004610	APR 02, 2008			
>ADD>			4144317	SEP 09, 1992		NDF	NOV 07, 1994
>ADD>	20165 002	NICOTINE; NICODERM	5004610	APR 02, 2008			
>ADD>			4144317	SEP 09, 1992		NDF	NOV 07, 1994

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>	20165 003	NICOTINE; NICODERM	5004610	APR 02, 2008			
>ADD>			4144317	SEP 09, 1992		NDF	NOV 07, 1994
>ADD>	19775 001	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL				NDF	JAN 29, 1995
>ADD>	19775 002	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL				NDF	JAN 29, 1995
>ADD>	20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
>ADD>	20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
>ADD>	19655 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
>DLT>	~~19655 001~~	~~ZIDOVUDINE; RETROVIR~~	~~4837208~~	~~FEB 02, 2005~~			
>ADD>			4833130	FEB 09, 2005		I-47	MAY 02, 1993
>DLT>			~~4833130~~	~~FEB 02, 2005~~		~~I-47~~	~~MAY 02, 1993~~
>ADD>			4828838	FEB 09, 2005		ODE	MAR 19, 1994
>DLT>			~~4828838~~	~~FEB 02, 2005~~		~~ODE~~	~~MAR 19, 1994~~
>ADD>			4724232	FEB 09, 2005		NCE	MAR 19, 1992
>DLT>			~~4724232~~	~~FEB 02, 2005~~		~~NCE~~	~~MAR 19, 1992~~
>ADD>	19910 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
>DLT>	~~19910 001~~	~~ZIDOVUDINE; RETROVIR~~	~~4837208~~	~~FEB 02, 2005~~			
>ADD>			4833130	FEB 09, 2005		ODE	MAR 19, 1994
>DLT>			~~4833130~~	~~FEB 02, 2005~~		~~ODE~~	~~MAR 19, 1994~~
>ADD>			4818538	FEB 09, 2005		I-47	MAY 02, 1993
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>ADD>			4724232	FEB 09, 2005		NCE	MAR 19, 1992
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>ADD>	19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
>DLT>	~~19951 001~~	~~ZIDOVUDINE; RETROVIR~~	~~4837208~~	~~FEB 02, 2005~~			
>ADD>			4833130	FEB 09, 2005		NCE	MAR 19, 1992
>DLT>			~~4833130~~	~~FEB 02, 2005~~		~~NCE~~	~~MAR 19, 1992~~
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>ADD>			4724232	FEB 09, 2005		ODE	MAR 19, 1994
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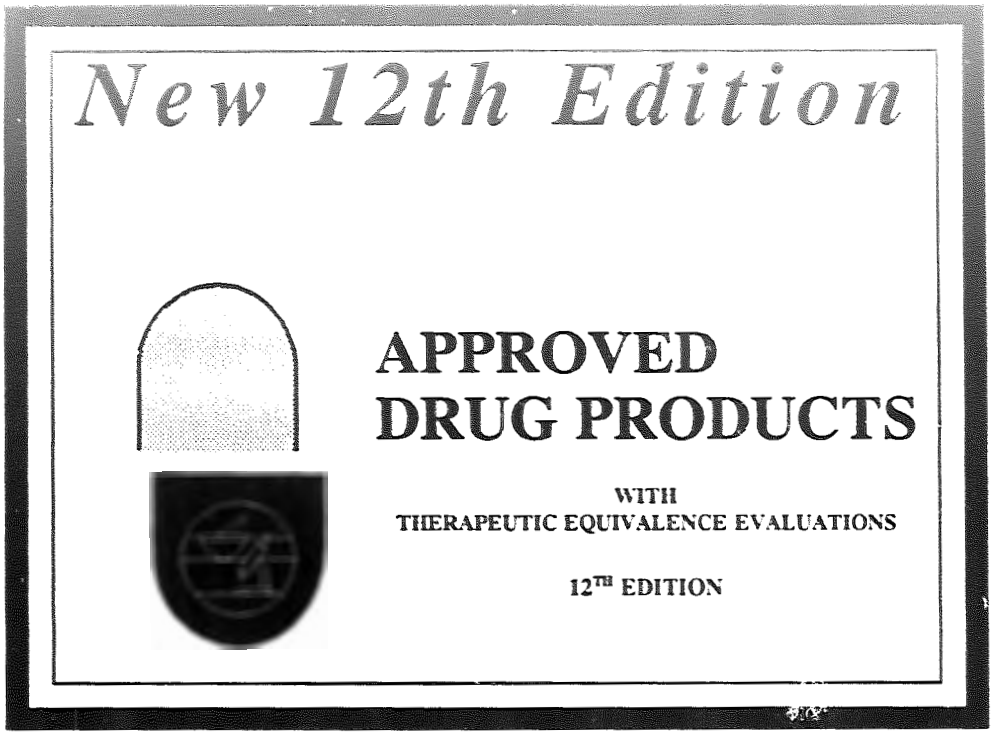

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