CUMULATIVE SUPPLEMENT 1 JAN'88

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

8TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVED DRUG PRODUCTS

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8TH EDITION

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JANUARY 1988

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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, 8th 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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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, List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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, List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act and the Patent and Exclusivity Data are indicated by the symbol (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 List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 8th 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 (ointment;topical)	SEP 3, 1986 (51 FR 31371)
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.

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 1987) 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[1]

CATEGORIES COUNTED	DEC 1987	MAR 1988	JUN 1988	SEP 1988
DRUG PRODUCTS LISTED	9709			
SINGLE SOURCE	2096 (21.6%)			
MULTISOURCE	7613 (78.4%)			
THERAPEUTICALLY EQUIVALENT	6691 (68.9%)			
NOT THERAPEUTICALLY EQUIVALENT	848 (8.7%)			
EXCEPTIONS[2]	74 (0.8%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	349			

(1) Cumulative counts are calculated from January 1, 1988 to, and including, the month indicated.
(2) Amino acid-containing products of varying composition (see Introduction, page I-8 of the List).

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

ACETAZOLAMIDE SODIUM

> ADD > AP	QUAD PHARMS	500MG/VIAL¤	N89619 001	JAN 13, 1988

DIAMOX

> ADD > AP	LEDERLE LABS	500MG/VIAL	N09388 001	

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

> ADD > AB	PHARM BASICS	EQ 12.5MG BASE;5MG¤	N70477 001	JAN 12, 1988
> ADD > AB		EQ 25MG BASE;10MG¤	N70478 001	JAN 12, 1988

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

COMPOUND 65

> DLT >/AA/	/BANMAX/	/389MG;32.4MG;65MG/	/N84553/002/	/AUG/17/1983/
> ADD > AA	∂ BANMAX	389MG;32.4MG;65MG	N84553 002	AUG 17, 1983

> ADD > ASPIRIN; HYDROCODONE BITARTRATE

TABLET; ORAL

AZDONE

> ADD >	CENTRAL PHARMS	500MG;5MG¤	N89420 001	JAN 25, 1988

BETAMETHASONE VALERATE

CREAM; TOPICAL

DERMABET

> ADD > AB	TARO PHARMS	EQ 0.1% BASE¤	N72041 001	JAN 06, 1988

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

ANCEF

> ADD > AP	SK&F LABS	EQ 5GM BASE/VIAL	N50461 004	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

> ADD > AP	ELKINS SINN	EQ 250MG BASE/VIAL¤	N62807 001	JAN 12, 1988
> ADD > AP		EQ 500MG BASE/VIAL¤	N62807 002	JAN 12, 1988
> ADD > AP		EQ 1GM BASE/VIAL¤	N62807 003	JAN 12, 1988
> ADD > AP		EQ 5GM BASE/VIAL¤	N62807 004	JAN 12, 1988
> ADD > AP		EQ 10GM BASE/VIAL¤	N62807 005	JAN 12, 1988
> ADD > AP		EQ 20GM BASE/VIAL¤	N62807 006	JAN 12, 1988

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

LYGEN

> DLT >/AB/	/BANMAX/	/5MG/	/N85107/002/	
> ADD > AB	∂ BANMAX	5MG	N85107 002	
> DLT >/AB/		/10MG/	/N85009/001/	
> ADD > AB	∂	10MG	N85009 001	
> DLT >/AB/		/25MG/	/N85108/001/	
> ADD > AB	∂	25MG	N85108 001	

DIAZOXIDE

INJECTABLE; INJECTION

DIAZOXIDE

> ADD > AP	QUAD PHARMS	15MG/ML¤	N71908 001	JAN 26, 1988

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL

> ADD > AB	LEDERLE LABS	EQ 10MG BASE¤	N71685 001	JAN 05, 1988
> ADD >				
> ADD > AB		EQ 25MG BASE¤	N71686 001	JAN 05, 1988
> ADD >				
> ADD > AB		EQ 50MG BASE¤	N71673 001	JAN 05, 1988
> ADD >				
> ADD > AB		EQ 75MG BASE¤	N71674 001	JAN 05, 1988
> ADD >				
> ADD > AB		EQ 100MG BASE¤	N71675 001	JAN 05, 1988
> ADD >				
> ADD > AB		EQ 150MG BASE¤	N71676 001	JAN 05, 1988
> ADD >				

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION
ERYTHROCIN

> ADD > AP	ABBOTT LABS	EQ 500MG BASE/VIAL¤	N62586 001	JAN 04, 1988
> ADD >				
> ADD > AP		EQ 1GM BASE/VIAL¤	N62586 002	JAN 04, 1988
> ADD >				

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

> ADD > AP	BEN VENUE LABS	50MG/ML¤	N89508 001	JAN 26, 1988
> ADD >				

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL

> ADD > AB	HALSEY DRUG	15MG¤	N71808 001	JAN 07, 1988
> ADD >				
> ADD > AB		30MG¤	N71809 001	JAN 07, 1988
> ADD >				

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

> DLT >/AP/	/PARKE/DAVIS/	/10MG/ML/	/N18420/001/	/FEB/26,/1982/
> DLT >				
> ADD > AP	WARNER CHILCOTT	10MG/ML	N18420 001	FEB 26, 1982
> ADD >				

TABLET; ORAL
FUROSEMIDE

> ADD > AB	BARR LABS	80MG¤	N70100 001	JAN 26, 1988
> ADD >				

HALOPERIDOL

TABLET; ORAL
HALOPERIDOL

> ADD > AB	BARR LABS	5MG¤	N71212 001	JAN 07, 1988
> ADD >				
> ADD > AB		10MG¤	N71173 001	JAN 07, 1988
> ADD >				
> ADD > AB		20MG¤	N71177 001	JAN 07, 1988
> ADD >				

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

> DLT >/AB/	/BANMAX/	/25MG/	/N86369/001/	
> ADD > AB	ə BANMAX	25MG	N86369 001	
> DLT >/AB/		/50MG/	/N83554/001/	
> ADD > AB	ə	50MG	N83554 001	

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

> ADD > AB	WARNER CHILCOTT	25MG;40MG¤	N71771 001	JAN 26, 1988
> ADD >				
> ADD > AB		25MG;80MG¤	N71772 001	JAN 26, 1988
> ADD >				

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

> ADD > AB	DANBURY PHARMA	50MG;75MG¤	N71969 001	APR 17, 1988 : JAN 15, 1988
> ADD >				

HYDROCORTISONE

LOTION; TOPICAL

> ADD >		BETA-HC			
> ADD >	AT	BETA DERM	1%	N89495 001	JAN 25, 1988
> ADD >					

IBUPROFEN

TABLET; ORAL

		IBUPROFEN			
> ADD >	AB	INVAMED	400MG	N72064 001	JAN 14, 1988
> ADD >					
> ADD >	AB		600MG	N72065 001	JAN 14, 1988
> ADD >					
> ADD >	AB		800MG	N71938 001	JAN 14, 1988
> ADD >					

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

		PRAMINE			
> DLT >	/AB/	/BANMAX/	/10MG/	/N83827/001/	
> ADD >	AB	ə BANMAX	10MG	N83827 001	
> DLT >	/AB/		/25MG/	/N83827/002/	
> ADD >	AB	ə	25MG	N83827 002	
> DLT >	/BP/		/50MG/	/N83827/003/	
> ADD >	BP	ə	50MG	N83827 003	

ISOSORBIDE DINITRATE

TABLET; ORAL

		ISOSORBIDE DINITRATE			
> ADD >	AB	BARR LABS	30MG	N87564 001	SEP 18, 1986
> ADD >					
> ADD >	AB	PAR PHARM	30MG	N87946 001	JAN 12, 1988

LORAZEPAM

TABLET; ORAL

		LORAZEPAM			
> ADD >	AB	WARNER CHILCOTT	1MG	N71038 001	JAN 12, 1988
> ADD >					
> ADD >	AB		2MG	N71039 001	JAN 12, 1988
> ADD >					

MAPROTILINE HYDROCHLORIDE

TABLET; ORAL

		MAPROTILINE HCL			
> ADD >	AB	AM THERPTCS	25MG	N72129 001	JAN 14, 1988
> ADD >					
> ADD >	AB		50MG	N72130 001	JAN 14, 1988
> ADD >					
> ADD >	AB		75MG	N72131 001	JAN 14, 1988
> ADD >					

METAPROTERENOL SULFATE

TABLET; ORAL

		ALUPENT			
> ADD >	AB	BOEHR INGEL	10MG	N15874 002	
> ADD >	AB		20MG	N15874 001	
> ADD >					
		METAPROTERENOL SULFATE			
> ADD >	AB	PHARM BASICS	10MG	N71013 001	JAN 25, 1988
> ADD >					
> ADD >	AB		20MG	N71014 001	JAN 25, 1988
> ADD >					

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

		AVENTYL HCL			
> ADD >	BD	LILLY	EQ 10MG BASE	N14684 001	
> ADD >	BD		EQ 25MG BASE	N14684 002	
> DLT >	/BP/		/EQ/10MG/BASE/	/N14684/001/	
> DLT >	/BP/		/EQ/25MG/BASE/	/N14684/002/	
		PAMELOR			
> ADD >	BD	SANDOZ PHARMS	EQ 10MG BASE	N18013 001	
> ADD >	BD		EQ 25MG BASE	N18013 002	
> DLT >	/BP/		/EQ/10MG/BASE/	/N18013/001/	
> DLT >	/BP/		/EQ/25MG/BASE/	/N18013/002/	

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

		PROPOXYPHENE HCL			
> DLT >	/AA/	/BANMAX/	/65MG/	/N83184/001/	
> ADD >	AA	ə BANMAX	65MG	N83184 001	

TEMAZEPAM

CAPSULE; ORAL
TEMAZEPAM

> ADD >	AB	CORD LABS	15MG¤	N71427 001	
> ADD >				JAN 12, 1988	
> ADD >	AB		30MG¤	N71428 001	
> ADD >				JAN 12, 1988	

THEOPHYLLINE

INJECTABLE; INJECTION
THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER

> ADD >	AP	TRAVENOL LABS	320MG/100ML	N18649 006
> ADD >				NOV 13, 1985

THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER

> ADD >	AP	ABBOTT LABS	320MG/100ML¤	N19211 006
> ADD >				JAN 20, 1988

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

> ADD >	AB	PHARM BASICS	100MG¤	N71355 001
> ADD >				JAN 11, 1988

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

> DLT >	/AB/	/BANMAX/	/500MG/	/N86141/001/
> ADD >	AB	@ BANMAX	500MG	N86141 001

URSODIOL

CAPSULE; ORAL
DEURSIL

> DLT >		/CIPHARMEX/	/150MG/	/N19594/001/
> DLT >				/DEC/31,/1987/
> ADD >		CIBA PHARM	150MG	N19594 001
> ADD >				DEC 31, 1987
> DLT >		/CIPHARMEX/	/300MG/	/N19594/002/
> DLT >				/DEC/31,/1987/
> ADD >		CIBA PHARM	300MG	N19594 002
> ADD >				DEC 31, 1987

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

> ADD >	AB	MUTUAL PHARM	80MG¤	N71488 001
> ADD >				JAN 13, 1988
> ADD >	AB		120MG¤	N71489 001
> ADD >				JAN 13, 1988

NO JANUARY 1988 APPROVALS

NO JANUARY 1988 APPROVALS

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

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).

ORPHAN DRUG EXCLUSIVE APPROVAL STATUS (CODED ODE) APPLIES ONLY TO THE APPROVED OR LICENSED INDICATION(S) FOR WHICH ORPHAN DRUG DESIGNATION HAS BEEN GRANTED PURSUANT TO SECTION 526 OF THE ACT.

FOR THE FOLLOWING DRUG PRODUCTS WITH ORPHAN DRUG EXCLUSIVE APPROVAL STATUS, THE SPONSOR HAS SEVEN YEARS OF EXCLUSIVE APPROVAL FOR THE APPROVED INDICATION BEGINNING ON THE DATE OF NDA, ANTIBIOTIC APPLICATION, OR BIOLOGICAL LICENSE APPROVAL FOR THE DRUG. NO SUBSEQUENT SPONSOR MAY RECEIVE APPROVAL OF AN NDA, BIOLOGICAL LICENSE, PAPER NDA, ANTIBIOTIC APPLICATION, ANDA, OR ABBREVIATED ANTIBIOTIC APPLICATION DURING THE SEVEN YEAR PERIOD FOR THE DRUG AND INDICATION(S) FOR WHICH ODE STATUS IS MAINTAINED UNLESS THE EXCLUSIVE APPROVAL HAS BEEN REVOKED AS DESCRIBED ABOVE OR THE SUBSEQUENT SPONSOR HAS OBTAINED WRITTEN CONSENT FROM THE SPONSOR WHO HAS RECEIVED EXCLUSIVE APPROVAL.

BIOLOGICAL PRODUCTS, ANTIBIOTICS, AND DRUGS THAT HAVE BEEN APPROVED UNDER SECTION 505 OR 507 OF THE ACT OR UNDER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT FOR MARKETING AND HAVE BEEN GIVEN ORPHAN DRUG EXCLUSIVE APPROVAL WILL BE NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION ADDENDUM. DRUG PRODUCTS THAT HAVE RECEIVED THE WRITTEN PERMISSION OF THE SPONSOR THAT HAS ORPHAN DRUG 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 ADDENDUM. THESE DRUG PRODUCTS DO NOT HAVE ANY EXCLUSIVE APPROVAL RIGHTS OF THEIR OWN, BUT CAN BE MARKETED BECAUSE OF THE CONSENT GIVEN BY THE SPONSOR THAT HAS EXCLUSIVE APPROVAL. THESE PRODUCTS ARE MARKED BY AN (*) NEXT TO THE APPLICANT'S NAME.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 8TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO JANUARY 1988 APPROVALS

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

NO JANUARY 1988 ACTIONS

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, 8TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NAME OF DRUG (DOSAGE FORM)	DATE	REVISED DATE
CARBAMAZEPINE (TABLET)	JAN 01, 1988	
CYCLOBENZAPRINE HYDROCHLORIDE (TABLET)	JAN 25, 1988	
INDOMETHACIN (CAPSULE)	JAN 27, 1988	

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, 8TH 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
CHLORZOXAZONE CAPSULE; ORAL	500MG	87 N-0032/ CP0006	MIKART	NEW DOSAGE FORM	APPROVED JAN 13, 1988

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/ML (1ML/VIAL) (2ML/VIAL)	87 P-0283/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	DENIED JAN 21, 1988
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	500MG/ML (1ML/VIAL) (2ML/VIAL)	87 P-0283/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	DENIED JAN 21, 1988

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, 8TH 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

PATENT USE CODE

U-26	METHOD OF TREATING ANIMALS SUFFERING FROM AN APPETITE DISORDER
U-27	METHOD OF BLOCKING THE UPTAKE OF MONOAMINES BY BRAIN NEURONS IN ANIMALS
U-28	METHOD FOR IMPROVING MEMORY IN MAMMALS
U-29	METHOD FOR TREATING AMNESIA
U-30	METHOD OF POTENTIATING CODEINE ANALGESIA IN MAMMALS

	APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4683235	JUL 28, 2004	U-30		
>ADD>			4647591	MAR 03, 2004	U-29		
>ADD>			4647591	MAR 03, 2004	U-28		
>ADD>			4626549	DEC 02, 2003	U-27		
>ADD>			4626549	DEC 02, 2003	U-26		
>ADD>			4194009	APR 19, 1994			
>ADD>	18677 001	NABILONE; CESAMET	4087545	MAY 02, 1997	U-7		
>DLT>	18677 001	NABILONE; CESAMET	4087545	MAY 02, 1997	U-7		
>ADD>	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 1998	U-5	NCE	AUG 07, 1992
>ADD>			4112097	SEP 05, 1995	U-5		
>ADD>			4026894	MAY 31, 1994			
>ADD>	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 1998	U-5	NCE	AUG 07, 1992
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>ADD>			4026894	MAY 31, 1994			
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