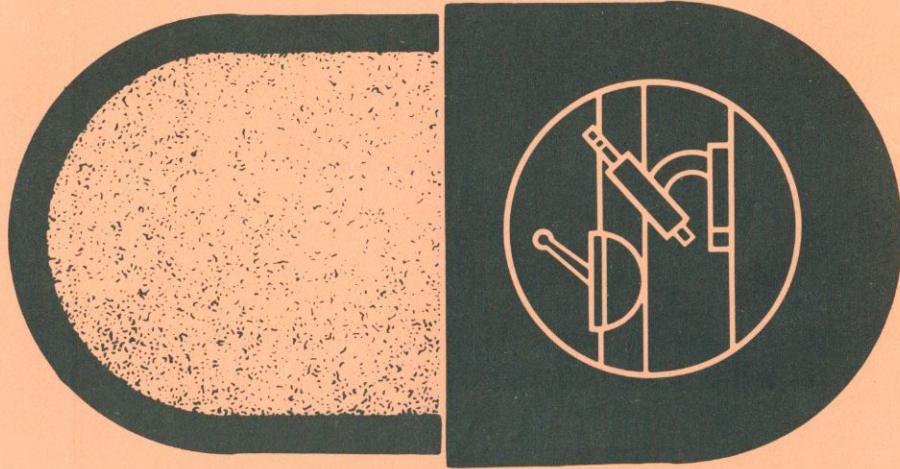


**CUMULATIVE
SUPPLEMENT 1**

JAN'91



APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

11TH EDITION

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS
11TH EDITION

CUMULATIVE SUPPLEMENT 1

JANUARY 1991

CONTENTS

	PAGE
1.0 INTRODUCTION	iii
1.1 How to Use the Cumulative Supplement	iii
1.2 Products Requiring Revised Labeling for Full Approval	v
1.3 Applicant (Name) Changes	v
1.4 Report of Counts for the Prescription Drug Product List	vi
2.0 DRUG PRODUCT LISTS	
2.1 Prescription Drug Product List	1
2.2 OTC Drug Product List	5
2.3 Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products List	6
2.4 Orphan Drug Product Designations	7
2.5 Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution	10
2.6 Biopharmaceutic Guidance Availability	11
2.7 ANDA Suitability Petitions	12
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Exclusivity Terms	13
B. Patent and Exclusivity Lists	14

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS
11TH EDITION
CUMULATIVE SUPPLEMENT 1
JANUARY 1991

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, 11th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, 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 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 " a " symbol to designate their non-marketed status. All products having a " a " symbol in the 12th Cumulative Supplement of the 11th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 12th 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.

<u>Products</u>	<u>Federal Register Reference</u>
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

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>ABBREVIATED NAME</u>
CORD LABORATORIES INC	GENEVA PHARMACEUTICALS INC	GENEVA
PHARMACIA LABORATORIES DIV PHARMACIA INC	KABI PHARMACIA	KABI

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 1990) 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

<u>CATEGORIES COUNTED</u>	<u>COUNTS CUMULATIVE BY QUARTER</u>		
	<u>DEC 1990</u>	<u>MAR 1991</u>	<u>JUN 1991</u>
DRUG PRODUCTS LISTED	10003		
SINGLE SOURCE	2090 (20.9%)		
MULTISOURCE	7913 (79.1%)		
THERAPEUTICALLY EQUIVALENT	7093 (70.9%)		
NOT THERAPEUTICALLY EQUIVALENT	685 (6.9%)		
EXCEPTIONS ¹	135 (1.3%)		
NEW MOLECULAR ENTITIES APPROVED	--		
NUMBER OF APPLICANTS	424		
		<u>SEP 1991</u>	

¹Amino acid-containing products of varying composition (see Introduction, page 1-8 of the List).

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 1 / JAN '91

DOXORUBICIN HYDROCHLORIDEINJECTABLE; INJECTIONADRIAMYCIN PFS

ADRIA

2MG/ML

N50629 001

DEC 23, 1987

200MG/100ML

N50629 002

MAY 03, 1988

2MG/ML

N63165 001

JAN 30, 1991

200MG/100ML

N63165 002

JAN 30, 1991

/2MG/ML/

/N50629/002/

/MAY/03, 1988/

DOXORUBICIN HCL

CETUS BEN VENUE

2MG/ML

N62975 001

MAR 17, 1989

PROPERIDOLINJECTABLE; INJECTIONPROPERIDOL

/ASTRA/

/2.5MG/ML/

/N72020/001/

/OCT/19, 1988/

N72020 001

OCT 19, 1988

2.5MG/ML

a ASTRA

ERGOLOID MESYLATESTABLET; SUBLINGUAL

/BRISTOL-MYERS/

/BRISTOL-MYERS/SQUIBB/1MG/

a BRISTOL MYERS SQUIBB 1MG

> DLT >

> ADD >

> ADD >

ERYTHROMYCINSOLUTION; TOPICALERYTHROMYCIN

CLAY PARK

2/2

N63038 001

JAN 11, 1991

> ADD >

> ADD >

ETODOLACCAPSULE; ORAL

LODINE

WYETH AVERST

200MG

N18922 002

JAN 31, 1991

300MG

N18922 003

JAN 31, 1991

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD > GALLIUM NITRATE> ADD > INJECTABLE; INJECTION

GANITE

FUJISAWA PHARM

25MG/ML

N19961 002

JAN 17, 1991

HALOBETASOL PROPIONATE

CREAM; TOPICAL

ULTRAVATE

/BRISTOL-MYERS/SQUIBB/0.05%/

/N19967/001/

/DEC/27, 1990/

N19967 001

DEC 27, 1990

WESTMOOD SQUIBB

0.05%

> DLT >

> DLT >

> ADD >

> ADD >

OINTMENT; TOPICAL

ULTRAVATE

/BRISTOL-MYERS/SQUIBB/0.05%/

/N19968/001/

/DEC/17, 1990/

N19968 001

DEC 17, 1990

WESTMOOD SQUIBB

0.05%

> DLT >

> DLT >

> ADD >

> ADD >

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

RESERPINE AND HYDROCHLOROTHIAZIDE

/SERRA/ /50MG;0.125MG/

/N88200/001/

/JAN/31, 1984/

N88200 001

JAN 31, 1984

a CORD

50MG;0.125MG

> DLT >

> DLT >

> ADD >

> ADD >

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HCL

/BARR/

/10MG/

/N88409/001/

/NOV/15, 1983/

N88409 001

NOV 15, 1983

> DLT >

> DLT >

> ADD >

> ADD >

LEVONORGESTREL

IMPLANT; IMPLANTATION

/LEVONORGESTREL/SYSTEM/

/WYETH-AVERST/ /36MG/IMPLANT/

/N20000/001/

/DEC/10, 1990/

> DLT >

> DLT >

> DLT >

LEVONORGESTREL

IMPLANT; IMPLANTATION
NORPLANT SYSTEM
MYETH AYERST

> ADD >
> ADD >
> ADD >

36MG/IMPLANT

N20088 001
DEC 10, 1990

PIPERAZINE CITRATE

SYRUP; ORAL

PIPERAZINE CITRATE

> DLT > /AB/
> ADD >

/EQ 500MG BASE/5ML/
EQ 500MG BASE/5ML

/N80774/001/
N80774 001

METAPROTERENOL SULFATE

TABLET; ORAL

METAPROTERENOL SULFATE
/AM/THERAP/

> DLT > /AB/
> DLT >
> ADD >
> ADD >
> ADD > AB
> ADD > AB
> ADD > AB
> ADD >

/20MG/
20MG

a AM THERAP

DANBURY

10MG

> ADD >

/N72055/001/
JUN 23, 1988
N72055 001
JUN 23, 1988
N73013 001
JAN 31, 1991
N72795 001
JAN 31, 1991

1.25MG

HOECHST ROUSSEL

2.5MG

5MG

10MG

N19901 001
JAN 28, 1991
N19901 002
JAN 28, 1991
N19901 003
JAN 28, 1991
N19901 004
JAN 28, 1991

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

ABBOTT

EQ 10MG BASE/2ML

EQ 10MG BASE/2ML

> ADD > AP
> ADD >
> ADD > AP
> ADD >

N71438 001
JAN 22, 1991

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

RITODRINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

30MG/100ML

ABBOTT

> ADD >
> ADD >
> ADD >

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL

SELENIUM SULFIDE

CLAY PARK

2.5%

N8996 001
JAN 10, 1991

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ZOFRAN

GLAXO

EQ 2MG BASE/ML

> ADD >
> ADD >
> ADD >
> ADD >

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL

PHENDIMETRAZINE TARTRATE

/105MG/
105MG

a VITARINE

/N18074/001/
N18074 001

> DLT > /BC/
> ADD >

INJECTABLE; INJECTION

SODIUM NITROPRUSSIDE

LYPHOMED

/50MG/VIAL/
50MG/VIAL

/N70031/001/
JAN 17, 1985

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 1 / JAN'91

> ADD > SUCCIMER

> ADD > CAPSULE; ORAL
> ADD > CHEMET
> ADD > MCNEIL
> ADD >

100MG

N19998 002
JAN 30, 1991

THIOTHIXENE

CAPSULE; ORAL
THIOTHIXENE
/AM/THERAP/

/2MG/

3 AM THERAP

2MG

/N71885/001/
/AUG/12, 1987/
N71885 001
AUG 12, 1987

> DLT > /AB/
> DLT >
> ADD >
> ADD >

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 1 / JAN '91

NO JANUARY 1991 APPROVALS

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 '91 - JAN '91

NO JANUARY 1991 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: CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TRADE: NOT ESTABLISHED	USE IN CONJUNCTION WITH GANCICLOVIR SODIUM FOR THE TREATMENT OF CYTOMEGALOVIRUS PNEUMONIA IN BONE MARROW TRANSPLANT PATIENTS.	MILES, INC
GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN TRADE: MEPIG	TREATMENT OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS.	UNIVAX BIOLOGICS, INC
GENERIC: RECOMBINANT HUMAN DEOXYRIBONUCLEASE (RHDNASE) TRADE: NOT ESTABLISHED	TO REDUCE MUCOUS VISCOSITY AND ENABLE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS.	GENENTECH, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-B4) TO B CELL (CD 19) TRADE: NOT ESTABLISHED	FOR THE EX-VIVO PURGING OF LEUKEMIC CELLS FROM THE BONE MARROW OF NON-T CELL ACUTE LYMPHOCTIC LEUKEMIA PATIENTS WHO ARE IN COMPLETE REMISSION.	IMMUNOGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (N901) TO CD56 POSITIVE CELLS TRADE: NOT ESTABLISHED	TREATMENT OF SMALL CELL LUNG CANCER.	IMMUNOGEN, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: CYSTEAMINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF NEPHROPATHIC CYSTINOSIS.	WARNER-LAMBERT COMPANY
GENERIC: DESMOPRESSIN ACETATE TRADE: DDAVP HIGH CONCENTRATION	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	ROPER PHARMACEUTICAL CORP
GENERIC: DRONABINOL TRADE: MARINOL	STIMULATION OF APPETITE AND PREVENTION OF WEIGHT LOSS IN PATIENTS WITH A CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	UNITED, INC
GENERIC: GALLIUM NITRATE TRADE: GANITE*/**	TREATMENT OF HYPERCALCEMIA OF MALIGNANCY. [JAN 17, 1998]	FUJISAWA PHARM
GENERIC: GENTAMICIN IMPREGNATED PMMA BEADS ON SURGICAL WIRE TRADE: SEPTOPAL	TREATMENT OF CHRONIC OSTEOMYELITIS OF POST-TRAUMATIC, POSTOPERATIVE OR HEMATOGENOUS ORIGIN.	E. MERCK, DARMSTADT
GENERIC: PENTOSTATIN TRADE: NOT ESTABLISHED	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA.	WARNER LAMBERT COMPANY
GENERIC: TESTOSTERONE SUBLINGUAL TRADE: NOT ESTABLISHED	TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY IN BOYS.	GYNEX, INC

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

NO JANUARY 1991 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, 11TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO JANUARY 1991 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, 11TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO JANUARY 1991 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, 11TH 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-44 RELIEF OF NAUSEA AND VOMITING
- U-45 TREATMENT OF INFLAMMATION AND ANALGESIA

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>	19926 001 ALTREXAMINE; HEXALEN				ODE	DEC 26, 1997
>ADD>	18723 001 DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
>ADD>	18723 002 DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
>ADD>	18723 003 DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
>ADD>	19680 001 DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
>ADD>	19794 001 DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008			
>ADD>	19794 002 DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008			
>ADD>	19668 001 DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
>ADD>	19668 002 DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
>ADD>	19668 003 DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
>ADD>	19668 004 DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
>ADD>	18922 001 ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
>ADD>		3939178	FEB 17, 1993		NCE	JAN 31, 1996
>ADD>	18922 002 ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
>ADD>		3939178	FEB 17, 1993		NCE	JAN 31, 1996
>ADD>	18922 003 ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
>ADD>		3939178	FEB 17, 1993		NCE	JAN 31, 1996
>ADD>	19961 002 GALLIUM NITRATE; GANITE				NCE	JAN 17, 1996
>ADD>	20007 001 ONDANSETRON HYDROCHLORIDE; ZOFRA				NCE	JAN 04, 1996
>ADD>		4753789	JUN 28, 2005	U-44		
>ADD>		4695578	SEP 22, 2004			
>ADD>	19901 001 RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	19901 002 RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	19901 003 RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	19901 004 RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	19998 002 SUCCIMER; CHEMET	4587258	MAY 06, 2003		NCE	JAN 30, 1996