CUMULATIVE SUPPLEMENT 1

JAN'93

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

Cumulative Supplement 1

January 1993

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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, 13th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

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

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing 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 13th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 14th 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 ABBREVIATED NAME)
RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV MCNEILAB (JOHNSON RW)	RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV ORTHO PHARMACEUTICAL CORP (JOHNSON RW)

1.4 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

The U.S. Pharmacopeia (USP) periodically makes additions to or changes in monograph titles. Some of these additions or changes may affect dosage form terms listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (ADP). Instead of making the change in each affected product, the Cumulative Supplement (CS) will list applicable monograph title and dosage form additions or changes in this section. These will appear as soon as the modified USP monograph title is official. It is possible for these additions or changes to be listed in this section before all applicant holders have made labeling modifications.

The monograph title additions or changes shown below will remain in this section in each succeeding supplement of this edition. Once the next edition of the ADP is published, the products affected by the title additions or changes will be displayed with the new dosage form in the appropriate drug list. As notification to the reader, these monograph title additions or changes will also be listed in a special section of the ADP.

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

FORMER USP MONOGRAPH TITLE (FORMER ADP DOSAGE FORM; ROUTE)	NEW USP MONOGRAPH TITLE (NEW ADP DOSAGE FORM; ROUTE)

THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF JANUARY 1993.

1.5 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 1992) 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 1992	MAR 1993	JUN 1993	SEP 1993
DRUG PRODUCTS LISTED	9488			
SINGLE SOURCE	2245 (23.7%)			
MULTISOURCE	7243 (76.3%)			
THERAPEUTICALLY EQUIVALENT	6516 (68.6%)			
NOT THERAPEUTICALLY EQUIVALENT	577 (6.1%)			
EXCEPTIONS[1]	150 (1.6%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	477			

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

> DLT >/AA/ /LUCHEN/ /500MG;5MG/ /N89907/001/
> DLT > /JAN/13,/1989/
> ADD > AA NORTON HN 500MG;5MG N89907 001
> ADD > JAN 13, 1989

TABLET; ORAL

ANEXSIA

> ADD > AA BOEHRINGER MANNHEIM 500MG;5MG N89160 001
> ADD > APR 23, 1987
> DLT >/AA/ /SKCP/ /500MG;5MG/ /N89160/001/
> DLT > /APR/23,/1987/

ANEXSIA 7.5/650

> ADD > AA BOEHRINGER MANNHEIM 650MG;7.5MG N89725 001
> ADD > SEP 30, 1987
> DLT >/AA/ /SKCP/ /650MG;7.5MG/ /N89725/001/
> DLT > /SEP/30,/1987/

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

> DLT >/AA/ /LUCHEN/ /500MG;5MG/ /N89696/001/
> DLT > /APR/21,/1988/
> ADD > AA NORTON HN 500MG;5MG N89696 001
> ADD > APR 21, 1988

AMINO ACIDS

INJECTABLE; INJECTION

> DLT > /NOVAMINE/8.5%/
> DLT > /KABIVITRUM/ /8.5%/ /N17957/002/
> DLT > /AUG/09,/1982/
> ADD > ∂ KABIVITRUM 8.5% N17957 002
> ADD > AUG 09, 1982
> ADD > TRAVASOL 10% IN PLASTIC CONTAINER
> ADD > BAXTER 10% N18931 003
> ADD > AUG 23, 1984
> DLT > /10%/ /N18931/004/
> DLT > /APR/27,/1988/
> DLT > /TRAVASOL/10%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/
> DLT > /BAXTER/ /10%/ /N18931/003/
> DLT > /AUG/23,/1984/
> ADD > TRAVASOL 5.5% IN PLASTIC CONTAINER
> ADD > BAXTER 5.5% N18931 001
> ADD > AUG 23, 1984
> DLT > /TRAVASOL/5.5%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/
> DLT > /BAXTER/ /5.5%/ /N18931/001/
> DLT > /AUG/23,/1984/
> ADD > TRAVASOL 8.5% IN PLASTIC CONTAINER
> ADD > BAXTER 8.5% N18931 002
> ADD > AUG 23, 1984

AMINO ACIDS

INJECTABLE; INJECTION

> DLT > /TRAVASOL/8.5%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/
> DLT > /BAXTER/ /8.5%/ /N18931/002/
> DLT > /AUG/23,/1984/

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION

ELAVIL

> DLT >/AP/ /MSD/ /10MG/ML/ /N12704/001/
> ADD > AP ZENECA 10MG/ML N12704 001

TABLET; ORAL

ELAVIL

> DLT >/AB/ /MSD/ /10MG/ /N12703/001/
> DLT >/AB/ /25MG/ /N12703/003/
> DLT >/AB/ /50MG/ /N12703/004/
> DLT >/AB/ /75MG/ /N12703/005/
> DLT >/AB/ /100MG/ /N12703/006/
> DLT >/AB/ /150MG/ /N12703/007/
> ADD > AB ZENECA 10MG N12703 001
> ADD > AB + 25MG N12703 003
> ADD > AB 50MG N12703 004
> ADD > AB 75MG N12703 005
> ADD > AB 100MG N12703 006
> ADD > AB 150MG N12703 007

AMOXICILLIN

CAPSULE; ORAL

TRIMOX

> DLT > /SQUIBB/ /250MG/ /N62098/001/
> DLT >/AB/ /250MG/ /N62152/001/
> DLT >/AB/ /500MG/ /N62098/002/
> DLT >/AB/ /500MG/ /N62152/002/
> ADD > ∂ APOTHECON 250MG N62098 001
> ADD > ∂ 250MG N62152 001
> ADD > ∂ 500MG N62098 002
> ADD > ∂ 500MG N62152 002

POWDER FOR RECONSTITUTION; ORAL

TRIMOX

> DLT > /SQUIBB/ /125MG/5ML/ /N62099/001/
> DLT >/AB/ /125MG/5ML/ /N62154/001/
> DLT >/AB/ /250MG/5ML/ /N62099/002/
> DLT >/AB/ /250MG/5ML/ /N62154/002/

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

> DLT >	/TRIMOX/			
> ADD >	ə APOTHECON	125MG/5ML	N62099 001	
> ADD >	ə	125MG/5ML	N62154 001	
> ADD >	ə	250MG/5ML	N62099 002	
> ADD >	ə	250MG/5ML	N62154 002	

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

> DLT >/AP/	/LILLY/	/EQ 500MG BASE/VIAL/	/N62565/001/	
> DLT >			/APR/04,/1985/	
> DLT >/AP/		/EQ 1GM BASE/VIAL/	/N62565/002/	
> DLT >			/APR/04,/1985/	
> DLT >/AP/		/EQ 2GM BASE/VIAL/	/N62565/003/	
> DLT >			/JUN/24,/1986/	
> ADD >	ə LILLY	EQ 500MG BASE/VIAL	N62565 001	
> ADD >			APR 04, 1985	
> ADD >	ə	EQ 1GM BASE/VIAL	N62565 002	
> ADD >			APR 04, 1985	
> ADD >	ə	EQ 2GM BASE/VIAL	N62565 003	
> ADD >			JUN 24, 1986	

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

> DLT >	/PRINCIPEN '250'/			
> DLT >/AB/	/SQUIBB/	/EQ 250MG BASE/	/N50056/001/	
> DLT >/AB/		/EQ 250MG BASE/	/N62157/002/	
> ADD >	ə APOTHECON	EQ 250MG BASE	N50056 001	
> ADD >	ə	EQ 250MG BASE	N62157 002	
> DLT >	/PRINCIPEN '500'/			
> DLT >/AB/	/SQUIBB/	/EQ 500MG BASE/	/N50056/002/	
> DLT >/AB/		/EQ 500MG BASE/	/N62157/001/	
> ADD >	ə APOTHECON	EQ 500MG BASE	N50056 002	
> ADD >	ə	EQ 500MG BASE	N62157 001	

POWDER FOR RECONSTITUTION; ORAL

> DLT >	/PRINCIPEN '125'/			
> DLT >/AB/	/SQUIBB/	/EQ 125MG BASE/5ML/	/N60127/002/	
> DLT >/AB/		/EQ 125MG BASE/5ML/	/N62151/001/	
> ADD >	ə APOTHECON	EQ 125MG BASE/5ML	N60127 002	
> ADD >	ə	EQ 125MG BASE/5ML	N62151 001	
> DLT >	/PRINCIPEN '250'/			
> DLT >/AB/	/SQUIBB/	/EQ 250MG BASE/5ML/	/N60127/001/	
> DLT >/AB/		/EQ 250MG BASE/5ML/	/N62151/002/	
> ADD >	ə APOTHECON	EQ 250MG BASE/5ML	N60127 001	
> ADD >	ə	EQ 250MG BASE/5ML	N62151 002	

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

> DLT >	/CAPSULE;/ORAL/		
> DLT >	/PRINCIPEN/W//PROBENECID/		
> DLT >	/;//SQUIBB/	/EQ/389MG/BASE;111MG/	/N50488/001/
> DLT >		/EQ/389MG/BASE;111MG/	/N62150/001/
> ADD >	ə APOTHECON	EQ 389MG BASE;111MG	N50488 001
> ADD >	ə	EQ 389MG BASE;111MG	N62150 001

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION

M.V.C. 943

> ADD > AP	FUJISAWA	10MG/ML;0.006MG/ML;0.5UGM/ML;		
> ADD >		1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;		
> ADD >		0.4MG/ML;0.36MG/ML;0.3MG/ML;		
> ADD >		330 UNITS/ML;1 IU/ML	N18440 002	
> ADD >			AUG 08, 1985	
> DLT >/AP/	/LYPHOMED/	/10MG/ML;0.006MG/ML;0.5UGM/ML;/		
> DLT >		/1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;/		
> DLT >		/0.4MG/ML;0.36MG/ML;0.3MG/ML;/		
> DLT >		/330 UNITS/ML;1 IU/ML/	/N18440/002/	
> DLT >			/AUG/08,/1985/	

BENZONATATE

CAPSULE; ORAL

BENZONATATE

> ADD > AA	PHARMACAPS	100MG	N81297 001	
> ADD >			JAN 29, 1993	

TESSALON

> ADD > AA	FOREST LABS	100MG	N11210 001

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE

> DLT >/AA/	/ZENITH/	/4MG/	/N84351/001/
> ADD >	ə ZENITH	4MG	N84351 001

CARISOPRODOL

TABLET; ORAL

> DLT >	/RELA/		
> DLT >/AA/	/SCHERING/	/350MG/	/N12155/001/
> ADD >	ə SCHERING	350MG	N12155 001

CEFOXITIN SODIUM

INJECTABLE; INJECTION
MEFOXIN IN PLASTIC CONTAINER

> ADD >	MERCK	EQ 20MG BASE/ML	N63182 001	
> ADD >			JAN 25, 1993	
> ADD >		EQ 40MG BASE/ML	N63182 002	
> ADD >			JAN 25, 1993	

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

> DLT > /BP/	/HEATHER/	/25MG/	/N85736/001/	
> ADD >	ə HEATHER	25MG	N85736 001	

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN

> DLT > /AP/	/FUJISAWA/	/1MG/ML/	/N83075/001/	
> ADD >	ə FUJISAWA	1MG/ML	N83075 001	

DEXAMETHASONE

SOLUTION; ORAL
/DEXAMETHASONE/

> DLT >	/ROXANE/	/0.5MG/5ML/	/N88248/001/	
> DLT >			/SEP/01,/1983/	
> ADD >	ə ROXANE	0.5MG/5ML	N88248 001	
> ADD >			SEP 01, 1983	

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM

> ADD > AP	MARSAM	5MG/ML	N72370 001	
> ADD >			JAN 29, 1993	
> ADD > AP		5MG/ML	N72371 001	
> ADD >			JAN 29, 1993	
> ADD > AP		5MG/ML	N72397 001	
> ADD >			JAN 29, 1993	

DIAZEPAM

TABLET; ORAL
DIAZEPAM

> DLT > /AB/	/ZENITH/	/2MG/	/N70360/001/	
> DLT >			/SEP/04,/1985/	
> DLT > /AB/		/5MG/	/N70361/001/	
> DLT >			/SEP/04,/1985/	
> ADD >	ə ZENITH	2MG	N70360 001	
> ADD >			SEP 04, 1985	
> ADD >	ə	5MG	N70361 001	
> ADD >			SEP 04, 1985	

DIAZOXIDE

CAPSULE; ORAL
PROGLYCEM

> ADD >	+ BAKER NORTON	50MG	N17425 001
> DLT >	/+//MEDCL/MKTG/	/50MG/	/N17425/001/

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
HYDROGENATED ERGOT ALKALOIDS

> DLT > /AA/	/ZENITH/	/0.5MG/	/N87186/001/	
> ADD >	ə ZENITH	0.5MG	N87186 001	

ERYTHROMYCIN

GEL; TOPICAL
ERYGEL

> DLT > /AT/	/HERBERT/	/2%/	/N50617/001/	
> DLT >			/OCT/21,/1987/	
> ADD > AT	+ HERBERT	2%	N50617 001	
> ADD >			OCT 21, 1987	
> ADD >	ERYTHROMYCIN			
> ADD > AT	STIEFEL	2%	N63211 001	
> ADD >			JAN 29, 1993	

> ADD > GADODIAMIDE

INJECTABLE; INJECTION
OMNISCAN

> ADD >	STERLING WINTHROP	287MG/ML	N20123 001
> ADD >			JAN 08, 1993

GEMFIBROZIL

CAPSULE; ORAL

> ADD >		GEMFIBROZIL			
> ADD >	AB	MYLAN	300MG	N73466 001	JAN 25, 1993
> ADD >					
> ADD >	AB	PUREPAC	300MG	N72929 001	JAN 29, 1993
> ADD >					
		LOPID			
> ADD >	AB +	PARKE DAVIS	300MG	N18422 002	

HYDROCORTISONE

CREAM; TOPICAL

> DLT >		HYDROCORTISONE		
> DLT >		BIOCRAFT	0.5%	N80400 002
> DLT >			1%	N80400 003
> DLT >			2.5%	N80400 004
> ADD >		∂ BIOCRAFT	0.5%	N80400 002
> ADD >		∂	1%	N80400 003
> ADD >		∂	2.5%	N80400 004

IBUPROFEN

TABLET; ORAL

> ADD >		IBUPROFEN			
> ADD >	AB	NORTON HN	400MG	N71145 001	SEP 23, 1986
> ADD >					
> ADD >	AB		600MG	N71146 001	SEP 23, 1986
> ADD >					
> ADD >	AB		800MG	N71769 001	MAY 08, 1987
> ADD >					
> DLT >		IFEN			
> DLT >	AB	LUCHEM	400MG	N71145 001	SEP 23, 1986
> DLT >					
> DLT >	AB		600MG	N71146 001	SEP 23, 1986
> DLT >					
> DLT >	AB		800MG	N71769 001	MAY 08, 1987
> DLT >					

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

> DLT >		ISOETHARINE HCL			
> DLT >	AN	ASTRA	0.125%	N87938 001	NOV 15, 1982
> DLT >					
> DLT >			0.062%	N87937 001	NOV 15, 1982
> DLT >					
> ADD >		∂ ASTRA	0.062%	N87937 001	NOV 15, 1982
> ADD >					
> ADD >		∂	0.125%	N87938 001	NOV 15, 1982
> ADD >					

ISOFLURANE

LIQUID; INHALATION

		FORANE			
> ADD >	AN +	ANAQUEST	99.9%	N17624 001	
> ADD >		ISOFLURANE			
> ADD >	AN	ABBOTT	99.9%	N74097 001	JAN 25, 1993
> ADD >					

ISOSORBIDE DINITRATE

TABLET; ORAL

		SORBITRATE			
> DLT >	AB	ICI	20MG	N86405 002	AUG 21, 1990
> DLT >					
> DLT >	AB		30MG	N88124 001	AUG 21, 1990
> DLT >					
> DLT >	AB		40MG	N88125 001	AUG 21, 1990
> DLT >					
> ADD >	AB	ZENECA	20MG	N86405 002	AUG 21, 1990
> ADD >					
> ADD >	AB		30MG	N88124 001	AUG 21, 1990
> ADD >					
> ADD >	AB		40MG	N88125 001	AUG 21, 1990
> ADD >					

KANAMYCIN SULFATE

INJECTABLE; INJECTION

> DLT >		KLEBCIL		
> DLT >	AP	SMITHKLINE/BEECHAM	EQ 75MG BASE/2ML	N62170 001
> DLT >	AP		EQ 500MG BASE/2ML	N62170 002
> DLT >	AP		EQ 1GM BASE/3ML	N62170 003
> ADD >		∂ SMITHKLINE BEECHAM	EQ 75MG BASE/2ML	N62170 001
> ADD >		∂	EQ 500MG BASE/2ML	N62170 002
> ADD >		∂	EQ 1GM BASE/3ML	N62170 003

KETOPROFEN

CAPSULE; ORAL
KETOPROFEN

>_ADD_>	AB	LEDERLE	25MG	N74014 001 JAN 29, 1993
>_ADD_>				
>_ADD_>	AB		50MG	N74014 002 JAN 29, 1993
>_ADD_>				
>_ADD_>	AB		75MG	N74014 003 JAN 29, 1993
>_ADD_>				

MANGANESE SULFATE

INJECTABLE; INJECTION
MANGANESE SULFATE

>_ADD_>		FUJISAWA	EQ 0.1MG MANGANESE/ML	N19228 001 MAY 05, 1987
>_ADD_>				
>_DLT_>		/LYPHOMED/	/EQ 0.1MG MANGANESE/ML/	/N19228/001/ /MAY 05, 1987/
>_DLT_>				

METRONIDAZOLE

TABLET; ORAL

>_DLT_>		/SAVAGE/		
>_DLT_>	/AB/	/SAVAGE/	/250MG/	/N70029/001/ /MAR 19, 1985/
>_DLT_>				
>_DLT_>	/AB/		/500MG/	/N70731/001/ /JUN 08, 1987/
>_DLT_>				
>_ADD_>		@ SAVAGE	250MG	N70029 001 MAR 19, 1985
>_ADD_>				
>_ADD_>		@	500MG	N70731 001 JUN 08, 1987
>_ADD_>				

NIACIN

TABLET; ORAL
NIACIN

>_DLT_>	/AB/	/ZENITH/	/500MG/	/N83180/001/
>_ADD_>		@ ZENITH	500MG	N83180 001

NITROFURANTOIN

TABLET; ORAL
NITROFURANTOIN

>_DLT_>	/AB/	/ZENITH/	/50MG/	/N80078/002/
>_DLT_>	/AB/		/100MG/	/N80078/001/
>_ADD_>		@ ZENITH	50MG	N80078 002
>_ADD_>		@	100MG	N80078 001

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
NITROFURANTOIN

>_ADD_>	AB	ZENITH	50MG	N73671 001 JAN 28, 1993
>_ADD_>				
>_ADD_>	AB		100MG	N73652 001 JAN 28, 1993
>_ADD_>				

NYSTATIN

CREAM; TOPICAL
NYSTATIN

>_ADD_>	AT	TARO	100,000 UNITS/GM	N64022 001 JAN 29, 1993
>_ADD_>				

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN

>_DLT_>	/AB/	/BIOCRAFT/	/200,000 UNITS/5ML/	/N60307/002/
>_ADD_>		BIOCRAFT	200,000 UNITS/5ML	N60307 002
>_DLT_>		/PENTIDS '200'/		
>_DLT_>	/AB/	/SQUIBB/	/200,000 UNITS/5ML/	/N62149/001/
>_ADD_>		@ APOTHECON	200,000 UNITS/5ML	N62149 001
>_DLT_>		/PENTIDS '400'/		
>_DLT_>	/AB/	/SQUIBB/	/400,000 UNITS/5ML/	/N62149/002/
>_ADD_>		@ APOTHECON	400,000 UNITS/5ML	N62149 002

TABLET; ORAL
PENICILLIN G POTASSIUM

>_ADD_>		@ APOTHECON	250,000 UNITS	N60392 003
>_DLT_>	/AB/	/SQUIBB/	/250,000 UNITS/	/N60392/003/
>_DLT_>		/PENTIDS '200'/		
>_DLT_>	/AB/	/SQUIBB/	/200,000 UNITS/	/N62155/001/
>_ADD_>		@ APOTHECON	200,000 UNITS	N62155 001
>_DLT_>		/PENTIDS '250'/		
>_DLT_>	/AB/	/SQUIBB/	/250,000 UNITS/	/N62155/002/
>_ADD_>		@ APOTHECON	250,000 UNITS	N62155 002
>_DLT_>		/PENTIDS '400'/		
>_DLT_>	/AB/	/SQUIBB/	/400,000 UNITS/	/N60392/004/
>_DLT_>	/AB/		/400,000 UNITS/	/N62155/003/
>_ADD_>		@ APOTHECON	400,000 UNITS	N60392 004
>_ADD_>		@	400,000 UNITS	N62155 003
>_DLT_>		/PENTIDS '800'/		
>_DLT_>	/AB/	/SQUIBB/	/800,000 UNITS/	/N60392/005/
>_DLT_>	/AB/		/800,000 UNITS/	/N62155/004/
>_ADD_>		@ APOTHECON	800,000 UNITS	N60392 005
>_ADD_>		@	800,000 UNITS	N62155 004

PENICILLIN G PROCAINE

INJECTABLE; INJECTION

> DLT >	/PURACILLIN A.S./				
> DLT >/AP/	/LILLY/	/300,000 UNITS/ML/	/N60093/001/		
> ADD >	@ LILLY	300,000 UNITS/ML	N60093 001		

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

	VEETIDS "125"				
> ADD >	@ APOTHECON	EQ 125MG BASE/5ML	N61206 001		
> DLT >/AA/	/SQUIBB/	/EQ 125MG BASE/5ML/	/N61206/001/		
	VEETIDS "250"				
> ADD >	@ APOTHECON	EQ 250MG BASE/5ML	N61206 002		
> DLT >/AA/	/SQUIBB/	/EQ 250MG BASE/5ML/	/N61206/002/		

TABLET; ORAL

> DLT >	/VEETIDS "250"/				
> DLT >/AB/	/SQUIBB/	/EQ 250MG BASE/	/N61164/001/		
> DLT >/AB/		/EQ 250MG BASE/	/N62156/002/		
> ADD >	@ APOTHECON	EQ 250MG BASE	N61164 001		
> ADD >	@	EQ 250MG BASE	N62156 002		
> DLT >	/VEETIDS "500"/				
> DLT >/AB/	/SQUIBB/	/EQ 500MG BASE/	/N61164/002/		
> DLT >/AB/		/EQ 500MG BASE/	/N62156/001/		
> ADD >	@ APOTHECON	EQ 500MG BASE	N61164 002		
> ADD >	@	EQ 500MG BASE	N62156 001		

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

	PHENTERMINE HCL				
> DLT >/AA/	/ZENITH/	/30MG/	/N86329/001/		
> ADD >	@ ZENITH	30MG	N86329 001		

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

> ADD >	K+8				
> ADD > AB	ALRA	8MEQ	N70998 001		
> ADD >			JAN 25, 1993		

PREDNISONE

TABLET; ORAL

	PREDNISONE				
> DLT >/AB/	/HEATHER/	/10MG/	/N84341/001/		
> DLT >/AB/		/20MG/	/N85543/001/		
> DLT >/AB/		/50MG/	/N86946/001/		
> ADD >	@ HEATHER	10MG	N84341 001		
> ADD >	@	20MG	N85543 001		
> ADD >	@	50MG	N86946 001		

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

	PROMETHAZINE HCL				
> DLT > /BP/	/ZENITH/	/50MG/	/N83613/001/		
> ADD >	@ ZENITH	50MG	N83613 001		

SODIUM CHLORIDE

INJECTABLE; INJECTION

	BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER				
> ADD > AP	FUJISAWA	9MG/ML	N88911 001		
> ADD >			FEB 07, 1985		
> DLT >/AP/	/LYPHOMED/	/2MG/ML/	/N88911/001/		
> DLT >			/FEB/07/1985/		

SULFISOXAZOLE

TABLET; ORAL

	SULFISOXAZOLE				
> DLT >/AB/	/HEATHER/	/500MG/	/N80189/001/		
> ADD >	@ HEATHER	500MG	N80189 001		

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

> DLT >	/TECHNETIUM/TC/99M/MAA/				
> DLT > /BS/	/MEDI/PHYSICS/	/N/A/	/N17773/001/		
> ADD >	@ MEDI PHYSICS	N/A	N17773 001		

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

> DLT >	/AB/	/ZENITH/	/100MG/	/N88273/001/
> DLT >				/OCT/03,/1983/
> ADD >		@ ZENITH	100MG	N88273 001
> ADD >				OCT 03, 1983

TRIFLUPROMAZINE

> DLT >		/SUSPENSION;/ORAL/		
> DLT >		/VESPRIN/		
> DLT >		/SQUIBB/	/EQ/50MG/HCL/5ML/	/N11491/004/
> ADD >		@ APOTHECON	EQ 50MG HCL/5ML	N11491 004

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

> ADD >		FUJISAWA	1MG/ML	N89515 001
> ADD >				APR 29, 1987
> DLT >		/LYPHOMED/	/1MG/ML/	/N89515/001/
> DLT >				/APR/29,/1987/

VITAMIN A PALMITATE

CAPSULE; ORAL

> ADD >		AFAXIN		
> ADD >		@ STERLING	EQ 50,000 UNITS BASE	N83187 001
		VITAMIN A		
> DLT >	/AA/	/ZENITH/	/EQ 50,000 UNITS BASE/	/N83190/001/
> ADD >		@ ZENITH	EQ 50,000 UNITS BASE	N83190 001

XENON, XE-133

GAS; INHALATION
XENON XE 133

> ADD >	AA	MEDI PHYSICS	10MCI/VIAL	N17687 002
> ADD >	AA		20MCI/VIAL	N17687 003

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	ISOCLOR		
>ADD<	CIBA	8MG;120MG	N18747 001
>ADD<			MAR 06, 1986
>DLT<	/FISONS/	/8MG;120MG/	/N18747/001/
>DLT<			/MAR/06,/1986/

IBUPROFEN

TABLET; ORAL

	IBUPROFEN		
>DLT<	/LUCHEM/	/200MG/	/N72901/001/
>DLT<			/DEC/19,/1991/
>DLT<		/200MG/	/N72903/001/
>DLT<			/DEC/19,/1991/
	IBUPROFEN		
>ADD<	NORTON HN	200MG	N71144 001
>ADD<			JAN 20, 1987
>ADD<		200MG	N72901 001
>ADD<			DEC 19, 1991
>ADD<		200MG	N72903 001
>ADD<			DEC 19, 1991
	IBUPROFEN		
>DLT<	/ZENITH/	/200MG/	/N71154/001/
>DLT<			/OCT/27,/1987/
>ADD<	@ ZENITH	200MG	N71154 001
>ADD<			OCT 27, 1987
>DLT<	/NEUVIL/		
>DLT<	/LUCHEM/	/200MG/	/N71144/001/
>DLT<			/JAN/20,/1987/

INDIUM IN^{111} CHLORIDE

SOLUTION; INJECTION
INDICLOR
AMERSHAM N/A N19862
DEC 29, 1992

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January, 1993]

NAME *Generic/Chemical* *TN=Trade Name*	INDICATION DESIGNATED	SPONSOR & ADDRESS *DD=Date Designated* *MA=Marketing Approval*
COLFOSCERIL PALMITATE, CETYL ALCOHOL, TYLOXAPOL TN= EXOSURF	TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 01/11/93 MA / /
CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR GENE TN=	TREATMENT OF CYSTIC FIBROSIS.	GENETIC THERAPY, INC. 19 FIRSTFIELD ROAD GAITHERSBURG MD 20878 DD 01/08/93 MA / /
INTERFERON BETA, RECOMBINANT HUMAN TN=	TREATMENT OF PRIMARY BRAIN TUMORS.	BIOGEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02142 DD 01/13/93 MA / /
MONOCLONAL ANTIBODY FOR IMMUNIZATION AGAINST LUPUS NEPHRITIS TN=	TREATMENT OF LUPUS NEPHRITIS.	MEDCLONE, INC. 2435 MILITARY AVENUE LOS ANGELES CA 90064 DD 01/07/93 MA / /
THALIDOMIDE TN=	TREATMENT OF THE CLINICAL MANIFESTATIONS OF MYCOBACTERIAL INFECTION CAUSED BY MYCOBACTERIUM TUBERCULOSIS AND NON-TUBERCULOUS MYCOBACTERIA.	CELGENE CORPORATION 7 POWDER HORN DRIVE WARREN NJ 07059 DD 01/12/93 MA / /
TRETINOIN TN= TRETINOIN LF, IV	TREATMENT OF ACUTE AND CHRONIC LEUKEMIA.	ARGUS PHARMACEUTICALS, INC. 3400 RESEARCH FOREST DRIVE THE WOODLANDS TX 77381 DD 01/14/93 MA / /
TUMOR NECROSIS FACTOR-BINDING PROTEIN 1 TN=	TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 COUNTS LESS THAN 200 CELLS PER MM3.	SERONO LABORATORIES, INC. 100 LONGWATER CIRCLE NORWELL MA 02061 DD 01/06/93 MA / /
TUMOR NECROSIS FACTOR-BINDING PROTEIN II TN=	TREATMENT OF SYMPTOMATIC PATIENTS WITH THE ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM3.	SERONO LABORATORIES, INC. 100 LONGWATER CIRCLE NORWELL MA 02061 DD 01/06/93 MA / /

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

NO JANUARY 1993 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTING. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE (HFD-650, MPN-2 ROOM 279) 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

TRIAZOLAM (TABLET)	DEC 24, 1992	

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHER LANE, ROCKVILLE, MD 20857.					
REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.					
CHLORPROMAZINE HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML	92 P-0284/ CP1	UDL	NEW STRENGTH	APPROVED JAN 07, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (12.5MG/VIAL)	92 P-0355/ CP1	LEDERLE	NEW STRENGTH	APPROVED JAN 07, 1993
LACTULOSE CRYSTAL; ORAL	10GM/PACKET	92 P-0370/ CP1	BENNETT AND COMPANY	NEW DOSAGE FORM	APPROVED JAN 07, 1993

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH 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-74	METHOD OF PROVIDING HYPNOTIC EFFECT
U-75	RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS
U-76	USE TO IMAGE A SUBJECT WITH A MAGNETIC RESONANCE IMAGING SYSTEM

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>	19604 001	ALBUTEROL SULFATE; VOLMAX	4851229	JUN 14, 2005			
>ADD>			4777049	OCT 11, 2005			
>ADD>			4751071	JUN 14, 2005			
>ADD>	19604 002	ALBUTEROL SULFATE; VOLMAX	4851229	JUN 14, 2005			
>ADD>			4777049	OCT 11, 2005			
>ADD>			4751071	JUN 14, 2005		NS	DEC 23, 1995
>ADD>	20045 001	AVOBENZONE; SHADE UVAGUARD	4387089	JUN 07, 2002			
>DLT>	~~20045 001~~	~~AVOBENZONE; SHADE UVAGUARD~~	~~4387089~~	~~JUN 07, 2000~~			
>ADD>	18651 001	DRONABINOL; MARINOL				ODE	DEC 22, 1999
>ADD>	18651 002	DRONABINOL; MARINOL				ODE	DEC 22, 1999
>ADD>	18651 003	DRONABINOL; MARINOL				ODE	DEC 22, 1999
>ADD>	20123 001	GADODIAMIDE; OMNISCAN	4687659	AUG 18, 2004	U-76	NCE	JAN 08, 1998
>ADD>	19891 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
>ADD>	19892 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
>ADD>	19700 001	KETOROLAC TROMETHAMINE; ACULAR	5110493	MAY 05, 2009	U-75	NCE	NOV 30, 1994
>ADD>			4454151	JUN 12, 2001	U-75	NDF	NOV 09, 1995
>ADD>			4089969	MAY 16, 1997	U-75		
>ADD>	18948 001	LEVOCARNITINE; CARNITOR				I-86	DEC 16, 1995
>ADD>	18948 002	LEVOCARNITINE; CARNITOR				I-86	DEC 16, 1995
>ADD>	20109 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
>DLT>	~~20109 001~~	~~NAFARELIN ACETATE; SYNAREL~~	~~4234571~~	~~NOV 18, 1997~~		~~NCE~~	~~FEB 13, 1995~~
>ADD>	20150 001	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
>ADD>	20150 002	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
>ADD>	20150 003	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
>ADD>	20066 001	NICOTINE POLACRILEX; NICORETTE DS				NCE	JAN 13, 1994
>ADD>	20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004		NCE	JAN 04, 1996
>ADD>	20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004		NCE	JAN 04, 1996
>ADD>	50689 001	RIFABUTIN; MYCOBUTIN				ODE	DEC 23, 1999
>ADD>	20080 001	SUMATRIPTAN SUCCINATE; IMITREX	4816470	MAR 28, 2006	U-72		
>ADD>	19908 001	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 10, 2000	U-74	NCE	DEC 16, 1997
>ADD>	19908 002	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 10, 2000	U-74	NCE	DEC 16, 1997

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19862	001	INDIUM 111 CHLORIDE; INDICLOR				NCE	DEC 29, 1997

*U.S. Government Printing Office: 1993 — 342-345/60008