

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

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FEDERAL BUREAU OF INVESTIGATION

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2009.

30th EDITION



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF PHARMACEUTICAL SCIENCE
OFFICE OF GENERIC DRUGS

2010

PRESCRIPTION DRUG PRODUCT LIST

Drug Name	Strength	Approval Number	Approval Date
<u>PAROXETINE HYDROCHLORIDE</u>			
TABLET; ORAL			
<u>PAROXETINE HYDROCHLORIDE</u>			
AB	TEVA	EQ 40MG BASE	
AB	ZYDUS PHARMS USA	EQ 10MG BASE	A076618 004 Aug 15, 2005
AB		EQ 20MG BASE	A077584 001 Mar 07, 2007
AB		EQ 30MG BASE	A077584 002 Mar 07, 2007
AB		EQ 40MG BASE	A077584 003 Mar 07, 2007
<u>PAXIL</u>			
AB	GLAXOSMITHKLINE	EQ 10MG BASE	A077584 004 Mar 07, 2007
AB		EQ 20MG BASE	N020031 001 Dec 29, 1992
AB		EQ 30MG BASE	N020031 002 Dec 29, 1992
AB +		EQ 40MG BASE	N020031 003 Dec 29, 1992
			N020031 005 Dec 29, 1992
TABLET, EXTENDED RELEASE; ORAL			
<u>PAROXETINE HYDROCHLORIDE</u>			
AB	MYLAN	EQ 12.5MG BASE	
AB		EQ 25MG BASE	A077873 001 Jun 29, 2007
AB	PAXIL CR	EQ 12.5MG BASE	A077873 002 Jun 29, 2007
AB	GLAXOSMITHKLINE	EQ 25MG BASE	N020936 001 Feb 16, 1999
AB			N020936 002 Feb 16, 1999
	PAXIL CR		
	+ GLAXOSMITHKLINE	EQ 37.5MG BASE	N020936 003 Dec 06, 2000
<u>PAROXETINE MESYLATE</u>			
TABLET; ORAL			
PEXEVA			
NOVEN THERAP			
		EQ 10MG BASE	N021299 001 Jul 03, 2003
		EQ 20MG BASE	N021299 002 Jul 03, 2003
		EQ 30MG BASE	N021299 003 Jul 03, 2003
		EQ 40MG BASE	N021299 004 Jul 03, 2003
<u>PAZOPANIB HYDROCHLORIDE</u>			
TABLET; ORAL			
VOTRIENT			
GLAXOSMITHKLINE			
		EQ 200MG BASE	N022465 001 Oct 19, 2009
		EQ 400MG BASE	N022465 002 Oct 19, 2009
<u>PEGADEMASE BOVINE</u>			
INJECTABLE; INJECTION			
ADAGEN			
		250 UNITS/ML	N019818 001 Mar 21, 1990
<u>PEGAPTANIB SODIUM</u>			
INJECTABLE; INTRAVITREAL			
MACUGEN			
		EQ 0.3MG ACID/0.09ML	N021756 001 Dec 17, 2004
<u>PEGVISOMANT</u>			
INJECTABLE; SUBCUTANEOUS			
SOMAVERT			
		10MG/VIAL	N021106 001 Mar 25, 2003
		15MG/VIAL	N021106 002 Mar 25, 2003
		20MG/VIAL	N021106 003 Mar 25, 2003
<u>PEMETREXED DISODIUM</u>			
INJECTABLE; IV (INFUSION)			
		EQ 100MG BASE/VIAL	N021462 002 Sep 07, 2003
		EQ 500MG BASE/VIAL	N021462 001 Feb 04, 2004

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>PAROXETINE MESYLATE - PEVEVA</u>						
NO21299 001	5874447	Jun 10, 2017		U-46		
	5874447	Jun 10, 2017		U-518		
	5874447	Jun 10, 2017		U-286		
	6703408	Oct 21, 2022	DP			
<u>PAROXETINE MESYLATE - PEVEVA</u>						
NO21299 002	5874447	Jun 10, 2017		U-286		
	5874447	Jun 10, 2017		U-46		
	5874447	Jun 10, 2017		U-518		
	6703408	Oct 21, 2022	DP			
<u>PAROXETINE MESYLATE - PEVEVA</u>						
NO21299 003	5874447	Jun 10, 2017		U-286		
	5874447	Jun 10, 2017		U-46		
	5874447	Jun 10, 2017		U-518		
	6703408	Oct 21, 2022	DP			
<u>PAROXETINE MESYLATE - PEVEVA</u>						
NO21299 004	5874447	Jun 10, 2017		U-286		
	5874447	Jun 10, 2017		U-46		
	5874447	Jun 10, 2017		U-518		
	6703408	Oct 21, 2022	DP			
<u>PAROPANIB HYDROCHLORIDE - VOTRIENT</u>						
NO22465 001	7105530	Dec 19, 2021	DS DP		NCE	Oct 19, 2014
	7262203	Dec 19, 2021	DS DP			
<u>PAROPANIB HYDROCHLORIDE - VOTRIENT</u>						
NO22465 002	7105530	Dec 19, 2021	DS DP		NCE	Oct 19, 2014
	7262203	Dec 19, 2021	DS DP			
<u>PEGAPTANIB SODIUM - MACUGEN</u>						
NO21756 001	5919455	Oct 27, 2013	DS		NCE	Dec 17, 2009
	5932462	Aug 03, 2016	DS			
	6011020	Jan 04, 2017	DS			
	6051698	May 19, 2015	DS	U-622		
	6113906	Oct 27, 2013	DS			
	6147204	Jun 11, 2010	DS			
	6426335	Jun 11, 2010		U-622		
<u>PEGVISOMANT - SOMAVERT</u>						
NO21106 001	5350836	Sep 27, 2011		U-507	ODE	Mar 25, 2010
	5681809	Sep 27, 2011		U-507		
	5849535	Mar 25, 2017	DS			
	5958879	Sep 27, 2011		U-507		
	6057292	Sep 21, 2015		U-507		
	6583115	Sep 27, 2011		U-507		
<u>PEGVISOMANT - SOMAVERT</u>						
NO21106 002	5350836	Sep 27, 2011		U-507	ODE	Mar 25, 2010
	5681809	Sep 27, 2011		U-507		
	5849535	Mar 25, 2017	DS			
	5958879	Sep 27, 2011		U-507		
	6057292	Sep 21, 2015		U-507		
	6583115	Sep 27, 2011		U-507		
<u>PEGVISOMANT - SOMAVERT</u>						
NO21106 003	5350836	Sep 27, 2011		U-507	ODE	Mar 25, 2010
	5681809	Sep 27, 2011		U-507		
	5849535	Mar 25, 2017	DS			
	5958879	Sep 27, 2011		U-507		
	6057292	Sep 21, 2015		U-507		
	6583115	Sep 27, 2011		U-507		
<u>PEMETREXED DISODIUM - ALIMTA</u>						
NO21462 001	5217974	Mar 29, 2011		U-551	I-601	Jul 02, 2012
	5344932	Jul 24, 2016	DS DP		I-571	Sep 26, 2011
					ODE	Feb 04, 2011

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<u>PEMETREXED DISODIUM - ALIMTA</u>						
N021462 002	5217974	Mar 29, 2011			I-601	Jul 02, 2012
	5344932	Jul 24, 2016	DS DP		I-571	Sep 26, 2011
					ODE	Feb 04, 2011
<u>PEMIROLAST POTASSIUM - ALAMAST</u>						
N021079 001	5034230	Jan 02, 2011		DP	U-184	
	5034230*PED	Jul 02, 2011			U-184	
<u>PENCICLOVIR SODIUM - DENAVIR</u>						
N020629 001	5075445	Sep 24, 2010				
	5840763	Sep 01, 2015			U-501	
	5866581	Sep 04, 2014			U-501	
	5916893	Sep 01, 2015			U-501	
	6124304	Sep 04, 2014			U-501	
	6469015	Oct 22, 2019			U-501	
	6573378	Sep 24, 2010				
	6579981	Jun 17, 2020			U-501	
<u>PENTETATE CALCIUM TRISODIUM - PENTETATE CALCIUM TRISODIUM</u>						
N021749 001					NCE	Aug 11, 2009
					ODE	Aug 11, 2011
<u>PENTETATE ZINC TRISODIUM - PENTETATE ZINC TRISODIUM</u>						
N021751 001					NCE	Aug 11, 2009
					ODE	Aug 11, 2011
<u>PENTOSAN POLYSULFATE SODIUM - ELMIRON</u>						
N020193 001	5180715	Jan 19, 2010			U-159	
<u>PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE - SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS</u>						
N021084 001	5607979	May 30, 2015				
<u>PERFLUTREN - DEFINITY</u>						
N021064 001	5547656	Apr 05, 2011				
	5769080	Jul 20, 2010				
	6033645	Jun 19, 2016			U-665	
	6146657	Dec 22, 2009	DS			
	6528039	Apr 05, 2011	DS			
	6773696	Apr 05, 2011	DS			
<u>PERGOLIDE MESYLATE - PERMAX</u>						
N019385 001	5114948	Oct 19, 2009				
<u>PERGOLIDE MESYLATE - PERMAX</u>						
N019385 002	5114948	Oct 19, 2009				
<u>PERGOLIDE MESYLATE - PERMAX</u>						
N019385 003	5114948	Oct 19, 2009				
<u>PERINDOPRIL ERBUMINE - ACEON</u>						
N020184 001	5162362	Nov 10, 2009	DS DP		U-531	
<u>PERINDOPRIL ERBUMINE - ACEON</u>						
N020184 002	5162362	Nov 10, 2009	DS DP		U-531	
<u>PERINDOPRIL ERBUMINE - ACEON</u>						
N020184 003	5162362	Nov 10, 2009	DS DP		U-531	
<u>PHENTOLAMINE MESYLATE - ORAVERSE</u>						
N022159 001	6764678	May 11, 2021			U-967	
	6872390	May 11, 2021		DP		
	7229630	Jun 20, 2023		DP		
	7569230	Oct 17, 2023			U-967	
	7575757	Apr 21, 2025		DP		

PATENT USE

- U-507 ACROMEGALY IN PATIENTS W/INADEQUATE RESPONSE TO SURGERY AND/OR RADIATION THERAPY AND/OR MEDICAL THERAPIES, OR FOR WHOM THESE THERAPIES ARE NOT APPROPRIATE
- U-508 METHOD OF RELEASING 17-BETA OESTRADIOL PRECURSOR IN A SUBSTANTIALLY ZERO ORDER PATTERN FOR AT LEAST THREE WEEKS
- U-509 TREATMENT OF CUTANEOUS MANIFESTATIONS OF CUTANEOUS T-CELL LYMPHOMA IN PATIENTS WHO ARE REFRACTORY TO AT LEAST ONE PRIOR SYSTEMIC THERAPY
- U-510 TOPICAL TREATMENT OF CUTANEOUS LESIONS IN PATIENTS WITH CUTANEOUS T-CELL LYMPHOMA (STAGE IA AND IB) WHO HAVE REFRACTORY OR PERSISTENT DISEASE AFTER OTHER THERAPIES OR WHO HAVE NOT TOLERATED OTHER THERAPIES
- U-511 USE OF QUINOLONE COMPOUNDS AGAINST ANAEROBIC PATHOGENIC BACTERIA
- U-512 USE OF QUINOLONE COMPOUNDS AGAINST ATYPICAL UPPER RESPIRATORY PATHOGENIC BACTERIA
- U-513 METHODS OF USE OF ANTIMICROBIAL COMPOUNDS AGAINST PATHOGENIC MYCOPLASMA BACTERIA
- U-514 PREVENTION OF OVULATION IN A WOMAN
- U-515 TREATMENT OF MULTIPLE MYELOMA PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES AND HAVE DEMONSTRATED DISEASE PROGRESSION ON THE LAST THERAPY
- U-516 METHOD OF TREATING A PSYCHOTIC DISEASE
- U-517 STABLE GEL FORMULATION FOR TOPICAL TREATMENT OF SKIN CONDITIONS
- U-518 OBSESSIVE COMPULSIVE DISORDER
- U-519 POST OPERATIVE NAUSEA AND VOMITING
- U-520 PREMENOPAUSAL OSTEOPOROSIS
- U-521 METHOD OF USING RIBAVIRIN IN COMBINATION WITH INTRON A (INTERFERON ALPHA-2 B RECOMBINANT) INJECTION TO TREAT PATIENTS WITH CHRONIC HEPATITIS C
- U-522 TREATMENT OF CMV RETINITIS BY INTRAVITREAL ADMIN OF A PHOSPHOROTHIOATE OLIGONUCLEOTIDE CAPABLE OF HYBRIDIZING WITH CMV MRNA
- U-523 METHOD OF TREATING INFECTION BY CRYPTOSPORIDIUM PARVUM IN AN IMMUNOCOMPROMISED MAMMAL
- U-524 METHOD OF TREATING DIARRHEA
- U-525 METHOD OF TREATING PARASITIC INFECTIONS
- U-526 METHOD OF PROVIDING CONTROLLED RELEASE OF A TREATING AGENT USING A CONTROLLED RELEASE COMPOSITION
- U-527 METHOD OF DELIVERING AN ACTIVE INGREDIENT USING A PROGRESSIVE HYDRATION BIOADHESIVE
- U-528 PREVENTION OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING
- U-529 ONCE DAILY TREATMENT OF ASTHMA WITH NEBULIZED BUDESONIDE
- U-530 TREATMENT OF HERPES ZOSTER, TREATMENT OF GENITAL HERPES, TREATMENT OF COLD SORES, SUPPRESSION OF GENITAL HERPES IN IMMUNOCOPETENT AND HIV-INFECTED INDIVIDUALS, REDUCTION OF RISK OF HETEROSEXUAL TRANSMISSION OF GENITAL HERPES
- U-531 TREATMENT OF PATIENTS WITH ESSENTIAL HYPERTENSION. MAY BE USED ALONE OR GIVEN WITH OTHER CLASSES OF ANTIHYPERTENSIVES, ESPECIALLY THIAZIDE DERIVATIVES
- U-532 TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD IN PATIENTS REQUIRING MORE THAN ONE BRONCHO DILATOR
- U-533 ERECTILE DYSFUNCTION
- U-534 HUMALOG IS AN INSULIN ANALOG THAT IS INDICATED IN THE TREATMENT OF PATIENTS WITH DIABETES MELLITUS FOR THE CONTROL OF HYPERGLYCEMIA
- U-535 TREATMENT OF SOCIAL ANXIETY DISORDER
- U-536 CONTRAST AGENT FOR MAGNETIC RESONACE IMAGING
- U-537 TREATMENT OF CONDITIONS RELATED TO HYPERALDOSTERONISM SUCH AS HYPERTENSION AND CARDIAC INSUFFICIENCY, WITH EPLERENONE
- U-538 FIRST LINE TREATMENT OF SEVERE HYPERTENSION, IN PATIENTS WITH HYPERTENSION SEVERE ENOUGH THAT THE VALUE OF ACHIEVING PROMPT BLOOD PRESSURE CONTROL EXCEEDS THE RISK OF INITIATING COMBINATION THERAPY IN THESE PATIENTS
- U-539 TREATMENT OF MODERATE TO SEVERE DEMENTIA OF THE ALZHEIMER'S TYPE
- U-540 TREATMENT OF FUNGAL INFECTIONS
- U-541 METHOD OF TREATMENT OF ADULTS INFECTED WITH HIV-1
- U-542 METHOD OF TREATING PATIENT WITH TYPE 2 DIABETES BY ONCE DAILY ADMINISTRATION
- U-543 TREATMENT OF SCHIZOPHRENIA
- U-544 TREATMENT OF OVERACTIVE BLADDER. TREATMENT OF URINARY INCONTINENCE.
- U-545 METHOD FOR THE PREVENTION AND/OR TREATMENT OF THROMBOTIC EPISODES, SUCH AS MYOCARDIAL INFARCTION, IN A HUMAN PATIENT AND METHOD FOR THE PREVENTION OF VENOUS THROMBOSIS IN A POSTOPERATIVE HUMAN PATIENT
- U-546 USE OF REPAGLINIDE IN COMBINATION WITH METFORMIN TO LOWER BLOOD GLUCOSE
- U-547 MAINTENANCE MONOTHERAPY FOR BIPOLAR DISORDER
- U-548 A METHOD OF REDUCING FLUSH IN AN INDIVIDUAL BEING TREATED FOR A LIPIDEMIC DISORDER AND EFFECTIVELY TREATING THE LIPIDEMIC DISORDER
- U-549 USE IN THE TREATMENT OF MEN WITH ADVANCED SYMPTOMATIC PROSTATE CANCER
- U-550 TREATMENT OF BIPOLAR DISORDER AND SCHIZOPHRENIA
- U-551 METHOD FOR REDUCING TOXICITY OF ALIMTA TREATED PATIENTS BY ADMINISTERING FOLIC ACID