APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

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

Teva – Fresenius

PRESCRIPTION DRUG PRODUCT LIST

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

	PAROXETINE HYDROCHLORIDE					
AB	TEVA	EQ 40MG BASE	A076618	004	Aug 15, 2005
AB	ZYDUS PHARMS USA	EQ 10MG BASE	A077584	001	Mar 07, 2007
AB		EQ 20MG BASE	A077584	002	Mar 07, 2007
AB		EQ 30MG BASE	A077584	003	Mar 07, 2007
AB		EQ 40MG BASE	A077584	004	Mar 07, 2007
	PAXIL				
AB	GLAXOSMITHKLINE	EQ 10MG BASE	N020031	001	Dec 29, 1992
AB		EQ 20MG BASE	N020031	002	Dec 29, 1992
AB		EQ 30MG BASE	N020031	003	Dec 29, 1992
AB +		EQ 40MG BASE	N020031	005	Dec 29, 1992

TABLET, EXTENDED RELEASE; ORAL

	PAROXETINE HYDROCHLORIDE				
AB	MYLAN	EQ 12.5MG BASE	A077873	001	Jun 29, 2007
AB		EQ 25MG BASE	A077873	002	Jun 29, 2007
	PAXIL CR				
AB	GLAXOSMITHKLINE	EQ 12.5MG BASE	N020936	001	Feb 16, 1999
AB		EQ 25MG BASE	N020936	002	Feb 16, 1999
	PAXIL CR				
	+ GLAXOSMITHKLINE	EQ 37.5MG BASE	N020936	003	Dec 06, 2000

PAROXETINE MESYLATE

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

PAZOPANIB HYDROCHLORIDE

TABLET; ORAL

	VOTRIENT				
	GLAXOSMITHKLINE	EQ 200MG BASE	N022465	001	Oct 19, 2009
	+	EQ 400MG BASE	N022465	002	Oct 19, 2009

PEGADEMASE BOVINE

INJECTABLE; INJECTION

	ADAGEN				
	+ ENZON PHARMS	250 UNITS/ML	N019818	001	Mar 21, 1990

PEGAPTANIB SODIUM

INJECTABLE; INTRAVITREAL

	MACUGEN				
	+ EYETECH INC	EQ 0.3MG ACID/0.09ML	N021756	001	Dec 17, 2004

PEGVISOMANT

INJECTABLE; SUBCUTANEOUS

	SOMAVERT				
	+ PHARMACIA AND UPJOHN	10MG/VIAL			
	+	15MG/VIAL	N021106	001	Mar 25, 2003
	+	20MG/VIAL	N021106	002	Mar 25, 2003
			N021106	003	Mar 25, 2003

PEMETREXED DISODIUM

INJECTABLE; IV (INFUSION)

	+ LILLY				
	+	EQ 100MG BASE/VIAL	N021462	002	Sep 07, 2007
		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
PAROXETINE MESYLATE - PEXEVA						
N021299 001	5874447	Jun 10, 2017	U-46			
	5874447	Jun 10, 2017	U-518			
	5874447	Jun 10, 2017	U-286			
	6703408	Oct 21, 2022	DP			
PAROXETINE MESYLATE - PEXEVA						
N021299 002	5874447	Jun 10, 2017	U-286			
	5874447	Jun 10, 2017	U-46			
	5874447	Jun 10, 2017	U-518			
	6703408	Oct 21, 2022	DP			
PAROXETINE MESYLATE - PEXEVA						
N021299 003	5874447	Jun 10, 2017	U-286			
	5874447	Jun 10, 2017	U-46			
	5874447	Jun 10, 2017	U-518			
	6703408	Oct 21, 2022	DP			
PAROXETINE MESYLATE - PEXEVA						
N021299 004	5874447	Jun 10, 2017	U-286			
	5874447	Jun 10, 2017	U-46			
	5874447	Jun 10, 2017	U-518			
	6703408	Oct 21, 2022	DP			
PAZOPANIB HYDROCHLORIDE - VOTRIENT						
N022465 001	7105530	Dec 19, 2021	DS DP		NCE	Oct 19, 2014
	7262203	Dec 19, 2021	DS DP			
PAZOPANIB HYDROCHLORIDE - VOTRIENT						
N022465 002	7105530	Dec 19, 2021	DS DP		NCE	Oct 19, 2014
	7262203	Dec 19, 2021	DS DP			
PEGAPTANIB SODIUM - MACUGEN						
N021756 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			
PEGVISOMANT - SOMAVERT						
N021106 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			
PEGVISOMANT - SOMAVERT						
N021106 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			
PEGVISOMANT - SOMAVERT						
N021106 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			
PEMETREXED DISODIUM - ALIMTA						
N021462 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

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
PEMETREXED DISODIUM - ALIMTA						
N021462 002	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
PEMIROLAST POTASSIUM - ALAMAST						
N021079 001	5034230	Jan 02, 2011	DP U-184			
	5034230*PED	Jul 02, 2011	U-184			
PENCICLOVIR SODIUM - DENAVIR						
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			
PENTETATE CALCIUM TRISODIUM - PENTETATE CALCIUM TRISODIUM						
N021749 001					NCE	Aug 11, 2009
					ODE	Aug 11, 2011
PENTETATE ZINC TRISODIUM - PENTETATE ZINC TRISODIUM						
N021751 001					NCE	Aug 11, 2009
					ODE	Aug 11, 2011
PENTOSAN POLYSULFATE SODIUM - ELMIRON						
N020193 001	5180715	Jan 19, 2010	U-159			
PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE - SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS						
N021084 001	5607979	May 30, 2015				
PERFLUTREN - DEFINITY						
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			
PERGOLIDE MESYLATE - PERMAX						
N019385 001	5114948	Oct 19, 2009				
PERGOLIDE MESYLATE - PERMAX						
N019385 002	5114948	Oct 19, 2009				
PERGOLIDE MESYLATE - PERMAX						
N019385 003	5114948	Oct 19, 2009				
PERINDOPRIL ERBUMINE - ACEON						
N020184 001	5162362	Nov 10, 2009	DS DP U-531			
PERINDOPRIL ERBUMINE - ACEON						
N020184 002	5162362	Nov 10, 2009	DS DP U-531			
PERINDOPRIL ERBUMINE - ACEON						
N020184 003	5162362	Nov 10, 2009	DS DP U-531			
PHENTOLAMINE MESYLATE - ORAVERSE						
N022159 001	6764678	May 11, 2021	U-967		NP	May 09, 2
	6872390	May 11, 2021	DP			
	7229630	Jun 20, 2023	DP			
	7569230	Oct 17, 2023	U-967			
	7575757	Apr 21, 2025	DP			

PATENT AND EXCLUSIVITY TERMS

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 AMYCOPLASMA 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