

New Drugs Approved in 2010

Brand Name	Generic Name	New Molecular Entity	New Biologic	Approval Date	Company	Indication	Route of Administration
Ampyra	dalfampridine	✓		1/22/2010	manufactured by Elan; distributed by Acorda	to improve walking in patients with multiple sclerosis	oral
Victoza	liraglutide	✓		1/25/2010	Novo Nordisk	to treat type 2 diabetes	injection
Vpriv	velaglucerase alfa	✓		2/26/2010	Shire Human Genetic	to treat children and adults with Type I Gaucher disease	intravenous
Carbaglu	carglumic acid	✓		3/18/2010	Orphan Europe	to treat N-acetylglutamate synthase (NAGS) deficiency	oral
Asclera	polidocanol	✓		3/30/2010	Chemisch Fabrik Kreussler	to treat small types of varicose veins when the aim of treatment is to improve appearance	injection
Zortress	everolimus	✓		4/20/2010	Novartis	to prevent transplant rejection of kidney transplant	oral
Natazia	dienogest; estradiol valerate	✓		5/6/2010	Bayer Healthcare	for oral contraception	oral
Jevtana Kit	cabazitaxel	✓		6/17/2010	sanofi aventis	for advanced, hormone-refractory, prostate cancer that has worsened during or after treatment with docetaxel; to be used in combination with prednisone	intravenous
Lastacaft	alcaftadine	✓		7/28/2010	Vistakon Pharms, Inc	for the prevention of itching associated with allergic conjunctivitis	eye drop

Source: FDA data

Company names listed in bold font are PhRMA members

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Ella	ulipristal acetate	✓		8/13/2010	Lab HRA Pharma	for emergency contraception	oral
Gilenya	fingolimod	✓		9/21/2010	Novartis	to reduce relapses and delay disability progression in patients with relapsing forms of multiple sclerosis	oral
Pradaxa	dabigatran etexilate mesylate	✓		10/19/2010	Boehringer Ingelheim	for the prevention of stroke and blood clots in patients with atrial fibrillation	oral
Latuda	luprasidone hydrochloride	✓		10/28/2010	Sunovion Pharma, Inc	for the treatment of schizophrenia in adults	oral
Teflaro	ceftaroline fosamil	✓		10/29/2010	Cerexa, Inc; marketed by Forest Labs		infusion
Egrifta	tesamorelin acetate	✓		11/10/2010	Theratechnologies	for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy	subcutaneous injection
Halaven	eribulin mesylate	✓		11/10/2010	Eisai Inc	for the treatment of patients with metastatic breast cancer who have previously received at least 2 chemotherapeutic regimens for the treatment of metastatic breast cancer	IV
Actemra	tocilizumab		✓ (CDER)	1/11/2010	Genentech	to treat adults with moderate to severe rheumatoid arthritis who have not adequately responded to or cannot tolerate other approved drug classes for rheumatoid arthritis	intravenous

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Xiaflex	collagenase clostridium histolyticum		✓ (CDER)	2/2/2010	Auxilium Pharmaceuticals	for the treatment of Dupuytren's contracture	injected into the hand
Pevnar 13	pneumococcal 13- valent vaccine		✓ (CBER)	2/24/2010	Wyeth , a subsidiary of Pfizer	for the prevention of invasive disease caused by 13 different serotypes of <i>Streptococcus pneumoniae</i>	intramuscular
Provenge	sipuleucel-T		✓ (CBER)	4/29/2010	Dendreon Corporation	for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer	intravenous
Lumizyme	alglucosidase alfa		✓ (CDER)	5/24/2010	Genzyme	for patients ages 8 years and older with late-onset Pompe disease	intravenous
Prolia	denosumab		✓ (CDER)	6/1/2010	Amgen	for postmenopausal women with osteoporosis who are at high risk for fractures	injection
Glassia	alpha-1-proteinase inhibitor		✓ (CBER)	7/1/2010	Kamada Ltd	treatment of chronic augmentation and maintenance therapy in individuals with emphysema due to congenital deficiency of alpha-1-proteinase inhibitor	intravenous

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Xeomin	incobotulinumtoxinA		✓ (CDER)	7/30/2010	Merz Pharms	for treatment of abnormal head position and neck pain that happens with cervical dystonia; for treatment of abnormal spasm of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (Botox)	intramuscular injection
Afluria	seasonal influenza vaccine		✓ (CBER)	7/30/2010	CSL Limited	for prevention of seasonal influenza infection	IM
Agriflu	seasonal influenza vaccine		✓ (CBER)	7/30/2010	Novartis Vaccines and Diagnostics	for prevention of seasonal influenza infection	IM
Fluarix	seasonal influenza vaccine		✓ (CBER)	7/30/2010	GlaxoSmithKline Biologicals	for prevention of seasonal influenza infection	IM
FluLaval	seasonal influenza vaccine		✓ (CBER)	7/30/2010	ID Biomedical Corporation	for prevention of seasonal influenza infection	IM
FluMist	seasonal influenza vaccine		✓ (CBER)	7/30/2010	MedImmune Vaccines	for prevention of seasonal influenza infection	IM
Fluvirin	seasonal influenza vaccine		✓ (CBER)	7/30/2010	Novartis Vaccines and Diagnostics	for prevention of seasonal influenza infection	IM
Fluzone	seasonal influenza vaccine		✓ (CBER)	7/30/2010	sanofi pasteur	for prevention of seasonal influenza infection	IM
Krystexxa	pegloticase		✓ (CDER)	9/14/2010	Savient Pharms	for the treatment of chronic gout in adult patients refractory to conventional therapy	intravenous

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