

New Medicines Approved in 2008

Brand Name	Generic Name	New Molecular Entity	New Biologic	Approval Date	Company	Indication	Route of Administration
Fluarix	influenza virus vaccine		✓ (CBER)	8/5/2008	GlaxoSmithKline	For active immunization of adults 18 years of age and older against influenza disease caused by influenza virus types A and B	IM
Fluvirin	influenza virus vaccine		✓ (CBER)	8/1/2008	Novartis	For immunization of persons 4 years of age and older against influenza virus disease caused by influenza virus subtypes A and type B contained in the vaccine	IM
Afluria	influenza virus vaccine		✓ (CBER)	7/30/2008	CSL Limited	For active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine	IM

Source: FDA data
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FluLaval	influenza virus vaccine		✓ (CBER)	7/28/2008	ID Biomedical Corporation of Quebec	For active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine	IM
FluMist	influenza virus vaccine, live, intranasal		✓ (CBER)	7/25/2008	MedImmune Vaccines	For the active immunization of individuals 2-49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine	intranasal
Fluzone	influenza virus vaccine		✓ (CBER)	7/14/2008	sanofi pasteur	For active immunization in persons 6 months of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine	IM
Eovist	gadoxetate disodium	✓		7/3/2008	Bayer	For intravenous use in T1-weighted magnetic resonance imaging (MRI) of the liver to detect and characterize lesions in adults with known or suspected focal liver disease	IV

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Kinrix	Diphtheria and Tetanus toxoids and Acellular Pertussis adsorbed, inactivated poliovirus	✓	(CBER)	6/24/2008	GlaxoSmithKline	For active immunization against diphtheria, tetanus, pertussis, poliomyelitis as the 5th dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the 4th dose in the inactivated poliovirus vaccine (IPV) series in children 4 through 6 years of age whose previous DTaP vaccine doses have been with INFANRIX and/or PEDIARIX for the first 3 doses and INFANRIX for the 4th dose	IM
Durezol	difluprednate	✓		6/23/2008	Sirion Therapeutics	Provides for the treatment of inflammation and pain associated with ocular surgery	

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Pentacel	Diphtheria and Tetanus toxoids and Acellular Pertussis adsorbed, inactivated poliovirus and Haemophilus b Conjugate vaccine		✓ (CBER)	6/20/2008	sanofi pasteur	For active immunization against diphtheria, tetanus, pertussis, poliomyelitis, and invasive disease caused by Haemophilus influenzae type b when administered to infants and children 6 weeks through 4 years of age (prior to 5th birthday)	IM
Entereg	alvimopan	✓		5/20/2008	Adolor; GlaxoSmithKline	To accelerate the restoration of normal bowel function in patients 18 years and up who have undergone partial large or small bowel resection surgery	oral
Relistor	methylnaltrexone bromide	✓		4/24/2008	Wyeth ; Progenics	To help restore bowel function in patients with late-stage, advanced illness who are receiving opioids on a continuous basis to help alleviate pain	injection
Cimzia	certolizumab pegol		✓ (CDER)	4/22/2008	UCB	For adults with moderate to severe Crohn's disease who have not responded to conventional therapies	injection

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Lexiscan	regadenoson	✓		4/10/2008	Astellas	For use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging (MPI) -- a test that detects and characterizes coronary artery disease -- in patients unable to undergo adequate exercise stress	IV
Treanda	bendamustin hydrochloride	✓		3/20/2008	Cephalon	For treatment of chronic lymphocytic leukemia	IV
Rotarix	rotavirus vaccine, live		✓ (CBER)	3/19/2008	GlaxoSmithKline	For the prevention of rotavirus in infants and children	oral
Pristiq	desvenlafaxine succinate	✓		2/29/2008	Wyeth	For the treatment of major depressive disorder	oral

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Arcalyst	rilonacept		✓ (CDER)	2/27/2008	Regeneron Pharmaceuticals	For the long-term treatment of 2 Cryopyrin-Associated Periodic Syndromes disorders: Familial Cold Auto-Inflammatory Syndrome and Muckle-Wells Syndrome	subcutaneous injection
Xyntha	antihemophilic factor (recombinant), plasma. Albumin free		✓ (CBER)	2/21/2008	Wyeth	For the control and prevention of bleeding, which can occur spontaneously or after an accident or injury in patients diagnosed with hemophilia A; also to help prevent surgical bleeding in this patient population	IV
Intence	etavirine	✓		1/18/2008	Tibotec, a division of Johnson & Johnson	For the treatment of HIV in adults who have failed treatment with other antiretrovirals	oral

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