

## NMEs Approved by FDA's CDER in Calendar Year 2011

Below is a list of the new molecular entities (NMEs) approved by the U.S. Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) in calendar year 2011.

Drug Name	Active Ingredient	Date Approved	What it's used for
<a href="#">Eylea</a>	afibercept	11/18	To treat patients with wet (neovascular) age-related macular degeneration (AMD), a leading cause of vision loss and blindness in Americans ages 60 and older.
<a href="#">Erwinaze</a>	asparaginase Erwinia chrysanthemi	11/18	To treat acute lymphoblastic leukemia (ALL), who have developed an allergy (hypersensitivity) to E. coli derived asparaginase and pegapargase chemotherapy drugs used to treat ALL.
<a href="#">Jakafi</a>	ruxolitinib	11/16	To treat patients with the bone marrow disease myelofibrosis.
<a href="#">Onfi</a>	clobazam	10/24	For use as an adjunctive (add-on) treatment for seizures associated with Lennox-Gastaut syndrome in adults and children 2 years of age and older.
<a href="#">Ferriprox</a>	deferiprone	10/14	To treat patients with iron overload due to blood transfusions in patients with thalassemia, a genetic blood disorder that causes anemia, who had an inadequate response to prior chelation therapy.
<a href="#">Xalkori</a>	crizotinib	08/26	To treat certain patients with late-stage (locally advanced or metastatic), non-small cell lung cancers (NSCLC) who express the abnormal anaplastic lymphoma kinase (ALK) gene.
<a href="#">Firazyr</a>	icatibant	08/25	For the treatment of acute attacks of a rare condition called hereditary angioedema (HAE) in people ages 18 years and older.
<a href="#">Adcetris</a>	brentuximab vedotin	08/19	For the treatment of Hodgkin lymphoma and ALCL (systemic anaplastic large cell lymphoma).
<a href="#">Zelboraf</a>	vemurafenib	08/17	To treat patients with late-stage (metastatic) or unresectable (cannot be removed by surgery) melanoma, the most dangerous type of skin cancer.
<a href="#">Brilinta</a>	ticagrelor	07/20	To reduce cardiovascular death and heart attack in patients with acute coronary syndromes (ACS).
<a href="#">Xarelto</a>	rivaroxaban	07/01	To reduce the risk of blood clots, deep vein thrombosis (DVT), and pulmonary embolism (PE) following knee or hip replacement surgery.
<a href="#">Arcapta</a> <a href="#">Neohaler</a>	indacaterol inhalation powder	07/01	For the long term, once-daily maintenance bronchodilator treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema.
<a href="#">Nulojix</a>	belatacept	06/15	To prevent acute rejection in adult patients who have had a kidney transplant.

## CDER NMEs of Calendar Year 2011 (cont.)

Drug Name	Active Ingredient	Date Approved	What it's used for
<a href="#">Potiga</a>	ezogabine	06/10	For use as an add-on medication to treat seizures associated with epilepsy in adults.
<a href="#">Dificid</a>	fidaxomicin	05/27	For the treatment of <i>Clostridium difficile</i> -associated diarrhea (CDAD).
<a href="#">Incivek</a>	telaprevir	05/23	To treat certain adults with chronic hepatitis C infection.
<a href="#">Edurant</a>	rilpivirine	05/20	For the treatment of HIV-1 infection in adults who have never taken HIV therapy.
<a href="#">Victrelis</a>	boceprevir	05/13	To treat certain adults with chronic hepatitis C.
<a href="#">Tradjenta</a>	linagliptin	05/02	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
<a href="#">Zytiga</a>	abiraterone acetate	04/28	In combination with prednisone (a steroid) to treat patients with late-stage (metastatic) castration-resistant prostate cancer who have received prior docetaxel (chemotherapy).
<a href="#">Caprelsa</a>	vandetanib	04/06	To treat adult patients with late-stage (metastatic) medullary thyroid cancer who are ineligible for surgery and who have disease that is growing or causing symptoms.
<a href="#">Horizant</a>	gabapentin enacarbil	04/06	A once-daily treatment for moderate-to-severe restless legs syndrome (RLS).
<a href="#">Yervoy</a>	ipilimumab	03/25	To treat patients with late-stage (metastatic) melanoma, the most dangerous type of skin cancer.
<a href="#">Gadavist</a>	gadobutrol	03/14	For use in patients undergoing magnetic resonance imaging (MRI) of the central nervous system.
<a href="#">Benlysta</a>	belimumab	03/9	To treat patients with active, autoantibody-positive lupus (systemic lupus erythematosus) who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives, and nonsteroidal anti-inflammatory drugs.
<a href="#">Daliresp</a>	roflumilast	02/28	To decrease the frequency of flare-ups (exacerbations) or worsening of symptoms from severe chronic obstructive pulmonary disease (COPD).
<a href="#">Edarbi</a>	azilsartan medoxomil	02/25	To treat high blood pressure (hypertension) in adults.
<a href="#">Viibryd</a>	vilazodone hydrochloride	01/21	To treat major depressive disorder in adults
<a href="#">Natroba</a>	spinosad	01/18	For the treatment of head lice infestation in patients ages 4 years and older.
<a href="#">Datscan</a>	ioflupane i-123	01/14	An imaging drug used to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS).