

## FDA-Approved Drugs in 2011

### Cardiology/Vascular Diseases

**Brilinta (ticagrelor)**; AstraZeneca; For the reduction of thrombotic events in patients with acute coronary syndrome, Approved July 2011

**Edarbyclor (azilsartan medoxomil and chlorthalidone)**; Takeda Pharmaceutical; For the treatment of hypertension, Approved December of 2011

**Xarelto (rivaroxaban)**; Janssen Pharmaceuticals; For the reduction in the risk of stroke and systemic embolism resulting from atrial fibrillation, Approved November 2011

### Dermatology/Plastic Surgery

**Firazyr (icatibant)**; Shire; For the treatment of acute attacks of hereditary angioedema, Approved August of 2011

**laViv (azficel-T)**; Fibrocell Science; For the improvement of nasolabial fold wrinkles in adults, Approved June 2011

### Endocrinology

**Tradjenta (linagliptin)**; Boehringer Ingelheim; For the treatment of type II diabetes, Approved May 2011

### Gastroenterology

**Dificid (fidaxomicin)**; Optimer Pharmaceuticals; For the treatment of Clostridium difficile-associated diarrhea, Approved May 2011

**Incivek (telaprevir)**; Vertex; For the treatment of genotype 1 chronic hepatitis C, Approved May 2011

**Victrelis (boceprevir)**; Merck; For the treatment of chronic hepatitis C genotype 1, Approved May 2011

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### Hematology

**Erwinaze (asparaginase Erwinia chrysanthemi)**; Eusa Pharma; For the treatment of acute lymphoblastic leukemia, Approved November of 2011

**Ferriprox (deferiprone)**; Apotex; For the treatment of transfusional iron overload due to thalassemia, Approved October 2011

**Jakafi (ruxolitinib)**; Incyte; For the treatment of myelofibrosis, Approved November 2011

**Soliris (eculizumab)**; Alexion; For the treatment of atypical hemolytic uremic syndrome, Approved September 2011

**Xarelto (rivaroxaban)**; Bayer; For the prophylaxis of deep vein thrombosis during knee or hip replacement surgery, Approved July 2011

### Immunology/Infectious Diseases

**Edurant (rilpivirine)**; Tibotec; For the treatment of HIV-1, Approved May 2011

**Nulojix (belatacept)**; Bristol-Myers Squibb; For the prevention of organ rejection following kidney transplant, Approved June 2011

### Nephrology/Urology

**Potiga (ezogabine)**; Valeant Pharmaceuticals; For the treatment of partial-onset seizures, Approved June 2011

### Oncology

**Adcretris (brentuximab vedotin)**; Seattle Genetics; For the treatment of Hodgkin lymphoma and anaplastic large cell lymphoma, Approved August 2011

**Afinitor (everolimus)**; Novartis; For the treatment of advanced pancreatic neuroendocrine tumors, Approved May 2011

**Xalkori (crizotinib)**; Pfizer; For the treatment of ALK+ non-small cell lung cancer, Approved August of 2011

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**Zelboraf (vemurafenib)**; Roche; For the treatment of BRAF + melanoma, Approved August of 2011

**Zytiga (abiraterone acetate)**; Centocor Ortho Biotech; For the treatment of prostate cancer, Approved May 2011

### Ophthalmology

**Eylea (aflibercept)**; Regeneron Pharmaceuticals; For the treatment of neovascular (wet) age-related macular degeneration, Approved November 2011

### Pulmonary/Respiratory Diseases

**Arcapta (indacaterol maleate inhalation powder)**; Novartis; For the treatment of airflow obstruction resulting from chronic obstructive pulmonary disease, Approved July 2011

### 2011 Recalls

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- December 21, 2011 **McNeil Recall of Motrin IB Tablets and Caplets**
- December 02, 2011 **Eagle Pharmaceuticals, Inc. Recalls 4 Lots of Argatroban Injection 50 mg/50 mL (1 mg/mL) Due to a Potential for Visible Particulates**
- October 19, 2011 **Insight Pharmaceuticals Recalls "Nostrilla Nasal Decongestant" Due To Bacterial Contamination**
- October 03, 2011 **Superior Metabolic Technologies Inc Recalls Uprizing 2.0 Because the Product Contains Superdrol, Which is a Synthetic Steroid, Making it an Unapproved New Drug**
- September 15, 2011 **Qualitest Pharmaceuticals Issues a Nationwide Voluntary Recall of Oral Contraceptives**
- August 24, 2011 **H and P Industries, Inc. Recalls All Lots of Povidone Iodine Swabsticks, Povidone Iodine Prep Solutions, Povidone Iodine Scrub Solutions, and Povidone Iodine Prep Gel**
- August 02, 2011 **American Regent, Inc. Initiates Voluntary Recall of Seventeen Lots of Vasopressin Injection, USP, Multiple Dose Vials Due to Sub-Potency**
- July 18, 2011 **American Regent Initiates Voluntary Nationwide Recall of Calcium Gluconate Injection, USP, 10%, 100 mL Pharmacy Bulk Package Due to Particulates**

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- **June 28, 2011 McNeil Consumer Healthcare Announces Voluntary Recall Of One Product Lot Of TYLENOL ® Extra Strength Caplets 225 Count Distributed In The U.S.**
- **June 24, 2011 Qualitest Pharmaceuticals Recalls Four Lots of Butalbital, Acetaminophen, and Caffeine Tablets, USP 50mg/325mg/40mg and Four Lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg**
- **June 24, 2011 Endo Pharmaceuticals Recalls Two Lots of Endocet (Oxycodone/Acetaminophen, USP) Tablets, 10 MG / 325 MG**
- **June 22, 2011 Nature Relief is Conducting a Voluntary Recall of Nature Relief Instant Wart and Mole Remover**
- **June 17, 2011 Ortho-McNeil-Janssen Pharmaceuticals, Inc. Voluntarily Recalls One Lot of RISPERDAL® Tablets and One Lot of Risperidone Tablets**
- **June 15, 2011 American Regent Recalls Concentrated Sodium Chloride Injection, USP, 23.4%, 30 mL Single Dose Vial Due to Particulates**
- **June 06, 2011 American Regent Recalls Methyldopate HCL Injection, USP 5 mL Single Dose Vial Due to Glass Particulates**
- **June 01, 2011 Aidapak Services, LLC Recalls ALL Repackaged Pharmaceuticals by Aidapak Services, LLC Due to Potential Cross Contamination with Beta Lactam Products**
- **May 19, 2011 American Regent Initiates Nationwide Voluntary Recall of Sterile Water for Injection, USP 50 mL Single Dose Vial Due to Particulate Matter**
- **May 05, 2011 American Regent Recalls Caffeine and Sodium Benzoate Injection, USP 250 mg/mL, 2 mL Single Dose Vial**
- **May 02, 2011 Bristol-Myers Squibb Recalls Coumadin (Warfarin Sodium) Crystalline 5 mg Tablets, Lot Number 9H49374A**
- **October 03, 2011 Superior Metabolic Technologies Inc Recalls Uprizing 2.0 Because the Product Contains Superdrol, Which is a Synthetic Steroid, Making it an Unapproved New Drug**