

FDA-Approved Drugs in 2012

Dermatology/Plastic Surgery

Sklice (ivermectin) lotion; Sanofi Pasteur; For the treatment of head lice, Approved February 2012

Endocrinology

Korlym (mifepristone); Corcept Therapeutics; For the control of hyperglycemia in adults with endogenous Cushing's syndrome, Approved February 2012

Hematology

Elelyso (taliglucerase alfa); Pfizer Inc; For the treatment of Gaucher disease, Approved May 2012

Omontys (peginesatide); Affymax; For the treatment of anemia due to chronic kidney disease, Approved March 2012

Musculoskeletal

Stendra (avanafil); Vivus; For the treatment of erectile dysfunction, Approved April 2012

Oncology

Afinitor (everolimus); Novartis Pharmaceuticals Corporation; For the treatment of renal angiomyolipoma associated with tuberous sclerosis complex, Approved April 2012

Erivedge (vismodegib); Genentech; For the treatment of basal cell carcinoma, Approved January 2012

Inlyta (axitinib); Pfizer; For the treatment of advanced renal cell carcinoma, Approved January 2012

Picato (ingenol mebutate) gel; LEO Pharma; For the treatment of actinic keratosis, Approved January 2012

Votrient (pazopanib); GlaxoSmithKline; For the treatment of soft tissue sarcoma, Approved April 2012

Ophthalmology

Zioptan (tafluprost ophthalmic solution); Merck; For the treatment of elevated intraocular pressure, Approved February 2012

Pediatrics/Neonatology

Surfaxin (lucinactant); Discovery Laboratories; For the treatment of respiratory distress syndrome in premature infants, Approved March 2012

Pharmacology/Toxicology

Voraxaze (glucarpidase); BTG International; For the treatment of toxic plasma methotrexate concentrations in patients with impaired renal function, Approved January 2012

Pulmonary/Respiratory Diseases

Kalydeco (ivacaftor); Vertex Pharmaceuticals; For the treatment of cystic fibrosis with the G551D mutation in the CFTR gene, Approved January of 2012

2012 Recalls

- May 25, 2012 **Franck's Pharmacy: Compounded Prescription Recall**
- May 12, 2012 **Hospira Recalls One Lot Of Hydromorphone Hydrochloride Injection 1 MG/ML, (C-II) 1 ML Fill In 2.5 ML Carpuject, That May Contain More Than The Intended Fill Volume**
- May 02, 2012 **Franck's Compounding Lab Recalls Triamcinolone acetonide P.F. 80mg/ml**
- April 24, 2012 **American Regent Recalls Epinephrine Injection, USP, 1:1000, 1mL Ampules Lot #1395 Due to Discoloration and Small Visible Particles**

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- April 19, 2012 **XROCK INDUSTRIES, LLC Recalls X-ROCK, a Product Marketed as a Dietary Supplement To Support Male Sexual Performance, Due to Unlisted, Potentially Hazardous Ingredient**
- April 17, 2012 **Hospira Recalls One Lot of Morphine Sulfate Injection, USP 4 MG/ML, (C-II) 1 ML Fill in 2.5 ML Carpuject, That May Contain More Than The Intended Fill Volume**
- March 31, 2012 **Franck's Lab Recalls One Lot of triamcinolone acetonide P.F. 80mg/ml**
- April 02, 2012 **American Regent Recalls Cyanocobalamin Injection, USP, 100 mcg/mL, 1ml Vial Lot #s 1662, 1679, 1683**
- March 09, 2012 **Recall of Brilliant Blue G**
- February 16, 2012 **Bedford Laboratories™ Issues Nationwide Voluntary Recall of Cytarabine for Injection, USP, 1 Gram per Vial**
- February 24, 2012 **Regeneca, Inc. Issues a Voluntary Nationwide Recall of All Lots of Single Capsule RegenErect Because of Potential Health Risks**
- February 24, 2012 **Glenmark Generics Inc. Recalls Seven Lots of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg (Generic) Due to Possibility of Out of Sequence Tablets**
- February 22, 2012 **American Regent Initiates Nationwide Voluntary Recall Of Phenylephrine HCl Injection, USP, 1% 5 mL Vial, Lot# 0693 Due To Visible Particles**
- February 17, 2012 **McNeil Consumer Healthcare Announces Voluntary Nationwide Recall of Infants' TYLENOL Oral Suspension, 1 oz. Grape Due to Dosing System Complaints**
- February 16, 2012 **Bedford Laboratories Issues Nationwide Voluntary Recall of Cytarabine for Injection, USP, 1 Gram per Vial**
- February 10, 2012 **Regeneca, Inc. Issues A Voluntary Nationwide Recall Of A Specific Lot Of RegenArouse Because Of Potential Health Risks**
- February 09, 2012 **Wholistic Herbs, Inc. Recalls "Koff & Kold" and "Kold Sore" Because Of Possible Health Risk**
- February 06, 2012 **North American Rescue, LLC Announces A Follow-Up to the Recall of Cricket Convenience Kits Related to Nationwide Recall of Triad Povidone Iodine Prep Pads**
- February 02, 2012 **Bedford Laboratories Issues A Voluntary Nationwide Patient Level Recall Of Acetylcysteine Solution, USP, LOT 1877093**
- January 31, 2012 **Pfizer Recalls Lo/Ovral-28 and Norgestrel/Ethinyl Estradiol Tablets Due to Possibility of Inexact Tablet Counts or Out of Sequence Tablets**
- January 27, 2012 **One Lot of Aveeno Baby Calming Comfort Lotion Recalled**
- January 27, 2012 **Cephalon, Inc. recalls Treanda® (bendamustine HCL) for Injection 25mg/Vial Due to Particulate Matter**
- January 19, 2012 **Perfect Image Solutions, LLC Issues Voluntary Recall of Unapproved Product Due to Potential Health Risk**

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- January 10, 2012 **Bedford Laboratories Issues Guidance On 2011 Voluntary Recall Of Polymyxin B For Injection USP And Vecuronium Bromide For Injection Related To Glass Particles**
- January 08, 2012 **Novartis Consumer Health Inc. Recalls Certain Over-The-Counter Products Due to Potential Presence Of Foreign Tablets Or Chipped Or Broken Tablets Or Gelcaps**

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