FDA Report to PharmPAC
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On November 21, Health and Human Services Secretary Mike Leavitt and FDA Commissioner Andrew von Eschenbach unveiled the FDA emblem at the opening of the new U.S. Food and Drug Administration office in Shanghai, China. The new office is part of FDA's new global strategy to ensure the safety of trillions of dollars of imports. FDA is opening two other district offices in Beijing and Guangzhou, China. FDA also announced various positions in Brazil, Chile, or Argentina, South America.

On November 20, FDA approved Eisai's Banzel (rufinamide) tablets 100 mg, 200 mg, and 400 mg for use as an adjunctive treatment for the debilitating, severe seizures associated with Lennox-Gastaut syndrome. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01914.html

On November 20, FDA granted accelerated approval of GlaxoSmithKline's Promacta (eltrombopag) tablets 25 mg and 50 mg for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Eltrombopag is an orally-administered thrombopoietin receptor agonist that stimulates bone marrow megakaryocytes to produce platelets. http://www.fda.gov/Cder/Offices/OODP/whatsnew/eltrombopag.htm

On November 24, FDA approved Johnson & Johnson's Tapentadol hydrochloride, an immediate-release oral tablet for the relief of moderate to severe acute pain. Tapentadol is a centrally-acting synthetic analgesic that is available in doses of 50 mg, 75 mg, or 100 mg. Tapentadol acts in two ways, opioid (narcotic) and non-opioid. It affects the brain and body primarily by activating opioid receptors in the brain, spinal cord and gastrointestinal tract. In addition, Tapentadol inhibits the reuptake of the brain chemical norepinephrine which possibly has an analgesic effect. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01916.html