FDA Report to PharmPAC
September 4, 2008
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On August 9, FDA notified healthcare professionals of the risk of muscle injury, rhabdomyolysis, which can lead to kidney failure or death, when simvastatin is used with amiodarone. http://www.fda.gov/medwatch/safety/2008/safety08.htm#Simvastatin

On August 12, FDA informed healthcare professionals of the risk of adverse injection site reactions (pain, swelling, tenderness, induration, bruising, pruritus, or redness) in patients receiving naltrexone. Naltrexone is administered as an intramuscular gluteal injection and should not be administered intravenously, subcutaneously, or inadvertently into fatty tissue.
http://www.fda.gov/medwatch/safety/2008/safety08.htm#naltrexone

On August 15, FDA approved Prestwick Pharmaceutical's Xenazine (tetrabenazine) for treating the involuntary jerky movements (chorea) in people with Huntington's disease. Xenazine works by decreasing dopamine at relevant synapses in the brain that interact with certain nerve cells, thereby decreasing the involuntary movements. Xenazine was approved with a Risk Evaluation and Mitigation Strategy to warn about its drug's risks.
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01874.html

On August 18, FDA alerted health care professionals of six reports of hemorrhagic or necrotizing pancreatitis in patients taking Byetta (exenatide). Byetta should be promptly discontinued if pancreatitis is suspected. FDA is working with Amylin Pharmaceuticals to add stronger and more prominent warnings in the product label about the risk of acute hemorrhagic or necrotizing pancreatitis.
http://www.fda.gov/cder/drug/InfoSheets/HCP/exenatide2008HCP.htm

On August 1, FDA approved The Medicines Company's Cleviprex (clevidipine butyrate) for the reduction of blood pressure when the use of oral therapy is not feasible or not desirable.

On August 22, FDA approved Amgen's Nplate (romiplostim) for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts. Nplate was approved with a Risk Evaluation and Mitigation Strategy including a Medication Guide for patients and requires that all prescribers and patients enroll in a special program to track the long term safety of Nplate therapy.
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01876.html

On August 25, FDA informed health care professionals of two new cases of progressive multifocal leukoencephalopathy (PML) in European patients receiving Tysabri (natalizumab) monotherapy for multiple sclerosis for more than one year. PML, which is usually fatal, is a known risk of Tysabri treatment, but previous cases in patients with multiple sclerosis were seen in combination with other immunomodulatory therapies. Prescribing information for Tysabri will be revised. Healthcare professionals should continue to monitor patients for sign and symptoms of PML. Additionally, Tysabri should not be infused if PML is suspected. http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tysabri2