FDA Report to PharmPAC
November 6, 2008
Compiled by CAPT Matthew Tarosky

Do you receive safety alerts for human medical products (biologics, devices, drugs, nutritionals, and cosmetics)? Sign up for MedWatch email updates at http://www.fda.gov/medwatch/safety.htm

On September 4, FDA notified health care professionals of the risk of possibly fatal fungal infections (pulmonary and disseminated histoplasmosis, coccidioidomycosis, blastomycosis and other opportunistic infections) associated with four tumor necrosis factor-alpha (TNF) blockers, Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), and Remicade (infliximab), widely used to treat rheumatoid arthritis and other serious illnesses.

Cimzia®


Enbrel®

Humira®

Remicade®

For patients taking TNF blockers who present with signs and symptoms of possible systemic fungal infection, such as fever, malaise, weight loss, sweats, cough, dypsnea, and/or pulmonary infiltrates, or other serious systemic illness with or without concomitant shock, healthcare professionals should ascertain if patients live in or have traveled to areas of endemic mycoses. For patients at risk of histoplasmosis and other invasive fungal infections, clinicians should consider empiric antifungal treatment until the pathogen(s) are identified.

On September 23, 2008, OSI Pharmaceuticals, Inc. and Genentech, Inc. notified healthcare professionals that cases of hepatic failure and hepatorenal syndrome, including fatalities, have been reported during use of Tarceva (erlotinib), particularly in patients with baseline hepatic impairment. Patients with hepatic impairment receiving Tarceva should be closely monitored during therapy and the product should be used with extra caution in patients with total bilirubin greater than three times the upper limit of normal. Dosing should be interrupted or discontinued if changes in liver function are severe, such as doubling of total bilirubin and/or tripling of transaminases in the setting of pretreatment values outside the normal range.
http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tarceva.

On October 10, FDA approved Watson Pharmaceuticals' Rapaflo (silodosin) 8 mg capsules for the treatment of symptoms due to benign prostatic hyperplasia (BPH). Rapaflo is administered once daily in men who do not suffer from kidney or liver impairment. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01902.html

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

On October 8, FDA notified healthcare professionals and consumers that the Consumer Healthcare Products Association (CHPA) is voluntarily modifying the product labels of nonprescription OTC cough and cold medicines to state "do not use" in children under 4 years of age. FDA supports this labeling change to help prevent and reduce misuse and to better inform consumers about the safe and effective use of these products for children. FDA continues to assess the safety and efficacy of these products and to revise its OTC list of approved ingredients and amounts for these medicines. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01899.html

On October 10, FDA licensed a blood product Kogenate FS to reduce the frequency of bleeding episodes and prevent joint damage in children with Hemophilia A. Kogenate FS is manufactured by Bayer Healthcare LLC. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01900.html

On October 10, FDA licensed Lev Pharmaceuticals' Cinryze, the first product in the United States intended to protect people with hereditary angioedema (HAE), a rare and potentially life-threatening genetic disease. Cinryze is licensed for the prevention of HAE attacks, which can occur spontaneously or during stress, surgery, or infection in patients diagnosed with the disease. Attacks can produce rapid swelling of the hands, feet, limbs, face, intestinal tract or airway. Swelling of the larynx can lead to asphyxiation. Cinryze is a C1-esterase inhibitor product derived from human plasma. This plasma protein regulates clotting and inflammatory reactions that, when impaired, can lead to local tissue swelling. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01903.html

On October 27, FDA approved Duramed Pharmaceutical's extended-cycle oral contraceptive, LoSeasonique (levonorgestrel/ethinyl estradiol tablets 0.10 mg/0.02 mg and ethinyl estradiol tablets 0.01 mg). Under the extended-cycle regimen, women take LoSeasonique for 84 consecutive days, followed by 0.01 mg ethinyl estradiol tablets for seven days.

On October 28, FDA approved Schwarz Biosciences' antiepilepsy medication, Vimpat (lacosamide) as an add-on treatment for partial-onset seizures in adults with epilepsy.

On October 31, FDA approved Schwarz Pharma's Toviaz (fesoterodine fumarate) 4 mg or 8mg extended release tablets for overactive bladder. Toviaz relaxes the smooth muscle tissue of the bladder, thus reducing the urinary frequency, urge to urinate, and sudden urinary incontinence. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01910.html