FDA Report to PharmPAC
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News

- Office of Regulatory Affairs (ORA) Reorganization: ORA, which encompasses some headquarters staff and all of the FDA regional and district offices plus resident posts, is proposing a restructuring that would eliminate the Central, Northeast, Pacific, Southeast, and Southwest Regional offices. Regional staff would be reassigned as appropriate. ORA is proposing the restructuring to be effective October 1, 2007.

Safety

- Novartis has withdrawn marketing of tegaserod maleate (Zelnorm®), a drug used for the short-term treatment of women with irritable bowel syndrome with constipation and for patients younger than 65 years of age with chronic constipation. FDA analysis of safety data pooled from 29 clinical trials involving over 18,000 patients showed an excess number of serious cardiovascular adverse events, including angina, heart attacks, and stroke, in patients taking Zelnorm compared to patients given placebo.
- Companies that manufacture and distribute pergolide (Permax) have agreed to withdraw this drug from the market due to the potential for heart valve damage. Two new studies showed that patients with Parkinson's disease who were treated with pergolide had an increased chance of serious damage to their heart valves when compared to patients who did not receive the drug. Pergolide is a member of a class of drugs known as dopamine agonists and is used with levodopa and carbidopa to manage the signs and symptoms (tremors and slowness of movement) of Parkinson's disease.