

**FDA Report to PharmPAC**  
**March 5, 2009**  
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On January 14, FDA launched a voluntary pilot program to help promote the safety of drugs and active drug ingredients produced outside the United States. FDA plans to select 100 applicants to participate in the Secure Supply Chain pilot program. To qualify, applicants will need to meet the pilot program's criteria, including a requirement that they maintain control over the drug products from the time of manufacture through entry into the country. <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01943.html>

On January 15, FDA opened two new foreign offices in New Delhi and Mumbai, India. These locations are now FDA's sixth and seventh foreign locations (after Beijing, Guangzhou, Shanghai, Brussels, and San José). Establishing a permanent FDA presence in India should greatly enhance the speed and effectiveness of regulatory cooperation with counterpart Indian agencies and industry that wish to export their products to the US, including inspections, and result in better efforts to protect consumers in both countries. FDA officials will also assist the Indian Government, as requested, in its ongoing efforts to improve its regulatory systems for exports to help assure product safety, and will work with regulated industry to help assure those wishing to export their products to the U.S. are fully cognizant of our requirements and expectations.

On January 14, FDA approved Savella (milnacipran hydrochloride) for the management of fibromyalgia.

On January 16, FDA licensed RiaSTAP (fibrinogen concentrate), an orphan drug for the treatment of bleeding in patients with a rare genetic defect known as congenital fibrinogen deficiency. RiaSTAP is an intravenous fibrinogen concentrate made from the plasma of healthy human blood donors. The drug is manufactured by CSL Behring of Marburg, Germany. <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01948.html>

On February 6, FDA approved ATryn (antithrombin recombinant), an anticoagulant used for the prevention of blood clots in patients with a rare disease known as hereditary antithrombin deficiency. ATryn is a therapeutic protein derived from the milk of genetically engineered goats. ATryn is manufactured by GTC Biotherapeutics, Inc. <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01952.html>

On February 13, FDA approved Takeda Pharmaceuticals' Uloric (febuxostat) for the management of gout. Uloric works by reducing uric acid levels. <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01964.html>