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FDA continues review of Crofelemer beyond goal date

06 September 2012 | Regulatory | By BioSpectrum Bureau

FDA continues review of Crofelemer by Salix beyond goal date

Mumbai: The Food and Drug Administration has advised Salix Pharmaceuticals, Mumbai-based Glenmark's collaborative partner, that the new drug application (NDA) for Crofelemer 125 mg tablets is still under review and that a final action will not be taken by the scheduled Prescription Drug User Fee Act (PDUFA) goal date of September 5, 2012. Glenmark has exclusive rights for Crofelemer in diarrhoea indications in nearly 140 countries, including India, and is the sole API supplier globally for Crofelemer (exChina).

Crofelemer 125 mg tablets is under US FDA review for symptomatic relief of noninfectious diarrhea in patients with HIV/AIDS on anti-retroviral therapy.

Salix in a note said: "The FDA continues to work collaboratively with Salix to progress this important product through its full review. By taking no action at this time, the FDA has allowed for the currently ongoing dialogue between Salix and the FDA to continue. The continuing dialogue should allow further collaboration between Salix and the agency, a collaboration that has resulted in substantial progress in handling topics important to crofelemer and botanical products in general. The primary topic is the production and control of the crofelemer active pharmaceutical ingredient, a complex mixture that is the first botanical product to be reviewed by the Agency for oral use. This focus is needed to ensure compliance with the manufacturing and product quality requirements of the Food, Drug & Cosmetic Act. Both Salix and FDA are committed to a robust level of cooperation and data exchange with the goal of providing crofelemer to patients suffering from this very important unmet need. Salix looks forward to this continuing collaboration and anticipate an action by FDA by the end of the first quarter of 2013."