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23 March 2016 | News | By BioSpectrum Bureau

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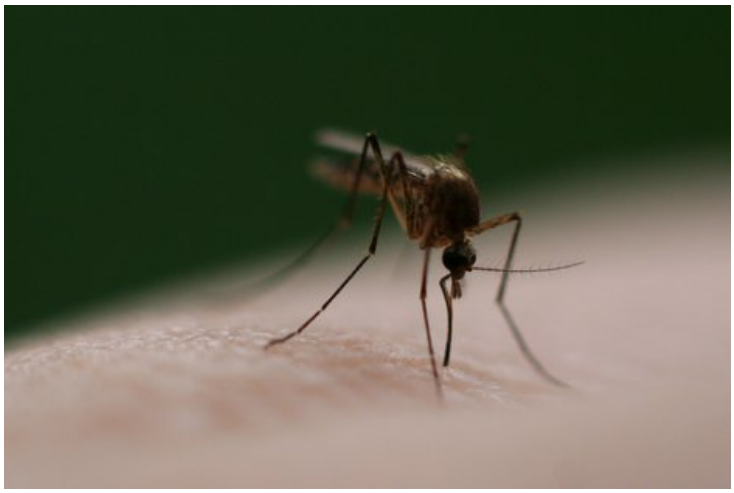

Glenmark Pharmaceuticals USA (Glenmark) has been granted final approval by the United States Food and Drug Administration (US FDA) for Raloxifene Hydrochloride Tablets USP, 60 mg, the therapeutic equivalent to the reference listed drug product, Evista Tablets, 60 mg, of Eli Lilly and Company.

According to IMS Health sales data for the 12 month period ending January 2016, the Evista Market achieved annual sales of approximately $336.5 million.

"Increased risk of deep vein thrombosis and pulmonary embolism have been reported with raloxifene hydrochloride. Women with active or past history of venous thromboembolism should not take raloxifene hydrochloride," Glenmark said in a warning, statement.

"Increased risk of death due to stroke occurred in a trial in postmenopausal women with documented coronary heart disease or at increased risk for major coronary events. Consider risk-benefit balance in women at risk for stroke," the company added.