Press release 4 August 2008

Registration application for azelastine Extra Strength submitted to the FDA

The registration application for azelastine nasal spray in the new formulation with Extra Strength has been submitted to the US Food and Drug Administration (FDA), seeking approval to treat symptoms of Seasonal Allergic Rhinitis and Perennial Allergic Rhinitis. The new formulation is patent pending. Six phase III studies evaluating efficacy and safety and a long term safety have been conducted involving about 1,600 patients treated with azelastine Extra Strength. The higher strength has been shown to offer additional symptom relief with maintained safety profile. In addition, the application seeks approval of a once or twice daily treatment regimen.

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