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Statement

Gurgaon (Haryana), India, November 6, 2014: Ranbaxy Laboratories Limited (Ranbaxy) has received communication from the US FDA wherein FDA has determined that Ranbaxy's ANDAs of concern did not have any data integrity issues. However, FDA has rescinded the previously granted tentative approvals for Ranbaxy's ANDAs for esomeprazole magnesium delayed-release capsules, 20 mg and 40 mg and for valganciclovir hydrochloride tablets USP, 450 mg. FDA has said that its original decisions granting tentative approvals were in error because of the compliance status of the facilities referenced in the ANDAs at the time the tentative approvals were granted. As a consequence, in FDA's view, Ranbaxy has forfeited its eligibility for 180-day exclusivity for its ANDA for valganciclovir hydrochloride tablets USP, 450 mg.

Ranbaxy is disappointed with this development and is actively evaluating all available options to preserve its rights.