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USFDA revokes approval for Ranbaxy's capsules

Special Correspondent

MUMBAI: In more trouble for Ranbaxy Laboratories, the U.S. Food and Drug Administration (FDA) has revoked the Indian company's 180-day exclusivity to market esomeprazole magnesium delayed release capsule 20 mg and 40 mg in the U.S.

Instead, the regulator has allowed Ivax Pharmaceuticals, Inc., a subsidiary of Teva Pharmaceuticals USA, to market esomeprazole in 20 and 40 mg capsules in the U.S. market.

On Monday, it had approved the first generic version of Nexium (esomeprazole magnesium delayed-release capsules) to treat gastroesophageal reflux disease (GERD) in adults and children. Esomeprazole is a proton pump inhibitor that reduces the amount of acid in the stomach.

Esomeprazole is used for treatment of stomach and esophagus problems.

Ranbaxy said it would take legal recourse.

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