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Ranbaxy loses 180-day exclusivity for generic Nexium

Will pursue legal options to preserve its rights

OUR BUREAU

New Delhi, January 27,

After losing the approval for manufacturing and selling esomeprazole magnesium delayed-release capsules (20 mg and 40 mg) in November, Ranbaxy Laboratories has now also lost the 180-days exclusivity for the medicine.

Generic versions

The drug-maker had received approval from the US Food and Drug Administration (FDA) to launch the first generic versions of AstraZeneca's heartburn medicine Nexium (esomeprazole magnesium) in 2008.

However, in November 2014, the US regulator withdrew that nod, saying the original decision to grant tentative approval was an "error" since at that time the company's facilities were under scrutiny.

Now, the FDA has informed the company that the six-month period of exclusivity for launching the generic equivalent of the medicine also stands cancelled.

Legal options

Ranbaxy said, on Tuesday, it will pursue "all available legal options to preserve its rights".

In 2008, the year Ranbaxy got approval for esomeprazole magnesium, the company had received two warning letters and the US FDA had issued import alerts against its facilities in Dewas (Madhya Pradesh) and Poanta Sahib (Himachal Pradesh).

The company was under fire for violations of several good manufacturing practices, manufacturing adulterated drugs and other issues.

Along with the withdrawal of approval for esomeprazole magnesium, the US FDA had also rescinded its nod to Ranbaxy for making the generic version of Roche's antiviral medicine, Valcyte (valganciclovir hydrochloride).

Later the regulator gave nod to Dr Reddy's Laboratories and Endo Pharmaceuticals for manufacturing the generic versions of this medicine.

Restraining order

Ranbaxy had sued the US FDA over this issue in the DC Federal Court and requested the court to issue restraining order against the US regulator from giving its approval to other ANDAs (abbreviated new drug applications) for generic versions of both Valcyte and Nexium.

The US court, however, refused to block the regulator from granting such approvals.

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