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Claris Life gets UK regulator's nod for Ahmedabad plant

Our Bureau

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Claris Lifesciences Ltd has said that its Ahmedabad plant has been approved by the UK's regulatory authority, the Medicines and Healthcare product Regulatory Agency (MHRA).

With this approval, Claris can re-launch its bag products in the European Union, the company said, adding that the approval is a step towards resolving the bag issue in totality.

Claris had recalled three of its products sold in bags from the US market, in June 2010. Following this recall, the MHRA had inspected the Claris plant in Ahmedabad between October 4-8, 2010.

This approval will benefit Claris as the EU is a lucrative market both in terms of revenue and margins, a note from the company said.

The European Union with approximately 24 per cent of the global injectable market is the second largest market in the world, after the US.

Recently, Claris had received approvals for its flagship product Propofol in the EU. The company has already received 137 approvals in Europe, while another 93 registrations are awaiting approvals, it added.

USFDA ISSUES

Claris is working with consultants towards resolving the US Food and Drug Administration-related issues, the corrective actions are on track and the company is confident of inviting the regulator for a re-audit and resolving the issue soon, the company said.

MHRA being a premier regulatory body, its approval to the manufacturing facility and bag-line, can be considered as a milestone towards resolving the US-FDA Issue, the company statement added.