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Amanta to reapply for US certification

Ahmedabad-based Amanta Healthcare (earlier Marck Biosciences) plans to appoint an external consultant to sort its US Food and Drug Administration (FDA) issues. It plans to reapply for certification in 12 months. Meanwhile, the company plans to prepare its response to the FDA warning letter to its Kheda (Gujarat) plant. Managing Director Bhavesh Patel said, "The FDA has suggested we appoint an external consultant to help us address the issues raised by the regulator. We plan to do that." He said while the FDA letter was dated July 8, the company had got it a few days back. So it would seek some time from the FDA to prepare its answers. Patel said while the FDA officials had visited the plant in November, the letter had come late. "We are puzzled why the FDA has issued this nine months after there was filing of our response and completion of compliance, validated by inspections by health authorities of other countries." He said as Amanta was currently not exporting to the US, the import alert will not have any practical impact.

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Regulatory