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Marck Biosciences gets warning letter from US FDA

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Gujarat-based Marck Biosciences has received a warning letter from the US Food and Drug Administration (US FDA) on its Kheda plant for alleged violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. The US regulator has also issued an import alert for the products manufactured at the Kheda facility.

In a letter to the company's managing director, Bhavesh Patel, the US FDA said: "During our October 29-November 1, 2013 inspection of your pharmaceutical manufacturing facility, Marck Biosciences Ltd located at Kheda, India, investigators from the US Food and Drug Administration (FDA) identified significant violations of current good manufacturing practice regulations for finished pharmaceuticals."

It added that these violations cause Marck's drug products to be adulterated. "Until all corrections have been completed and FDA has confirmed corrections of the violations and your firm's compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug product manufacturer. In addition, your failure to correct these violations may result in FDA continuing to refuse admission of articles manufactured at Marck Biosciences in Kheda, India, into the United States," the FDA said in the letter.

The US FDA has also noted that after reviewing the firm's responses in November 2013, felt that it was lacking sufficient corrective action. The FDA has asked the company to describe the controls in place to prevent data manipulation by its operators and supervisors.

FDA investigators identified two maintenance log books that included multiple entries describing significant equipment malfunctions, but for which no investigation into the potential effect on product quality was performed. It noted: "Your firm failed to ensure that each person engaged in the manufacture, processing, packing, or holding of a drug product has the education, training, and experience, or any combination thereof, to enable that person to perform his or her assigned functions."

Regulatory