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Comply or face action: US FDA tells Indian drugmakers

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Singapore: With increasing number of non-compliance issues being logged against Indian drugmakers by the US FDA, this time the American regulatory body has instructed the companies to either comply or face action.

US FDA has said that they are finding contaminants like filth, pesticides and insect parts in drugs manufactured in India, however such problems have emerged from other countries as well.

The FDA has yet against sounded a warning of 'appropriate action' against the companies that fail to implement 'Good Manufacturing Practices.'

This month, Wockhardt and Fresenius Kabi received warning letters from the FDA on lapses in good manufacturing practices while Hospira Healthcare India and RPG Life Sciences received warnings in May.

Last week, the FDA clamped down on 15 companies globally and India's Amrutam Life Care was one of them. The company was under fire for illegal sale of drugs labeled as dietary supplement and ayurvedic products for treating diabetes.

FDA spokesperson Mr Christopher C Kelly told PTI, "India has been a consistent provider of low-cost and quality medical products for many countries of the world. FDA seeks to ensure that Indian manufacturing facilities importing to the US understand the risks associated with their product's processes and assure they remain compliant to FDA's regulations."

Mr Kelly further added that the FDA has encountered problems like adulteration with contaminants that should not be found in manufacturing units, like microbiological agents like salmonella and listeria, or products identified with unapproved chemicals or pesticides and even presence of filth such as foreign bodies and insect parts.

FDA has further pointed out that issues associated with quality systems implementation, data integrity and validation of various processes used in manufacturing or testing have been found in India's manufacturing units.