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Pfizer halts production at India injectables plant, FDA finds issues

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Singapore –Pfizer has again suspended production at a long-troubled sterile injectables plant in India (Hospira) that the FDA has twice before cited for manufacturing and testing issues.

The agency recently outlined problems in a highly redacted, 32-page Form 483 following an inspection of the plant in Irungattukottai, India, a facility that was cited with a Form 483 two years ago and with a warning letter in 2013.

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Pfizer bought Hospira in 2015 for $15 billion to get its biosimilars program and its large manufacturing network for generic hospital injectables. At the time of the deal, it assured investors and the FDA that it could fix the manufacturing problems that had long plagued Hospira's manufacturing operations.