Clindamycin Injection ADD-Vantage Vials by Alvogen: Recall – Lack of Sterility Assurance" FDA (2017).

FDA report "Alvogen is voluntarily recalling seven lots of Clindamycin Injection USP ADD-Vantage Vials to the hospital/retail level due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the product. Clindamycin Injection is manufactured for Alvogen by Hospira Inc., a Pfizer Company.

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In the event that impacted product is administered, there is a reasonable probability that the patient may experience adverse events, ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. To date, Alvogen has not received any reports of adverse events associated with use of the product."

Full Alert

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