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Singapore: National Institutes of Health (NIH) Clinical Center has suspended operations of its Pharmaceutical Development Section (PDS) due to the discovery of serious manufacturing problems and lack of compliance with standard operating procedures.

Upon receipt of a complaint, Food and Drug Administration (FDA) representatives inspected the PDS between May 19 and May 29, and found a series of deficiencies that will require the NIH Clinical Center to take a number of corrective actions.

The facility makes products for certain clinical research studies conducted in the hospital and collaborating facilities. In April, two vials of albumin, used for the administration of the drug interleukin in experimental studies, were found to have fungal contamination. Vials made from the same batch were administered to six patients, although it is unknown whether those or other vials were contaminated. The six patients have been notified and are being followed closely for any signs of infection. At this time, none has developed signs of infection or illness.

"This is a distressing and unacceptable situation," said Dr Francis S Collins, Director, NIH. "The fact that patients may have been put in harm's way because of a failure to follow standard operating procedures in the NIH Clinical Center's Pharmaceutical Development Section is deeply troubling. I will personally oversee the steps to protect the safety of patients and remedy the situation as swiftly as possible."

Among the problems the FDA identified in their inspection were deficiencies in the physical facility, including flaws in the air handling system, and operational failures including inadequate quality control, insufficient employee training, and lack of compliance with standard operating procedures.