

# US research center suspends activities after 'deficiencies' found

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A top US federal research center has suspended some activities after the discovery of serious manufacturing problems and other issues requiring corrective actions, health officials said Thursday.

The National Institutes of Health (NIH) Clinical Center, located outside Washington, said it had suspended operations at its Pharmaceutical Development Section after Food and Drug Administration (FDA) investigators found "a series of deficiencies."

The problems center around two vials of albumin, used in the administration of the drug interleukin in studies, which in April were found to be contaminated with fungus.

"Vials made from the same batch were administered to six patients, although it is unknown whether those or other vials were contaminated," the NIH said.

"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."

The research center announced a series of steps including the suspension of making products and the testing of materials for contamination.

FDA inspectors also found other problems including deficient cleaning and disinfecting systems.

"This is a distressing and unacceptable situation," NIH director Francis Collins said in a statement.

"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."

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