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Contamination shuts down NIH pharmacy centre

US Food and Drug Administration finds fungus and insects in lab that supplies drugs for clinical trials.

Sara Reardon

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A facility at the US National Institutes of Health (NIH) that makes drugs for the agency's clinical trials has been shut down after government inspectors found fungal contamination and poor manufacturing practices.

The Pharmaceutical Development Section, located on the NIH's campus in Bethesda, Maryland, produces and manages experimental drugs for the agency's Clinical Center. As many as 46 ongoing trials receive materials from the facility, the NIH says.

“Out of an abundance of caution, we've suspended use of all these products,” says Lawrence Tabak, principal deputy director of the NIH. The agency is also monitoring six patients who received injections of the protein albumin from a batch in which at least two vials were contaminated with fungus.

Inspectors from the US Food and Drug Administration (FDA) investigated the NIH facility between 19 and 29 May in response to an anonymous complaint. In reports dated 29 May and 2 June, the FDA outlines numerous problems with quality control and staff training.

The FDA inspectors saw lab employees wearing garments that left parts of their arms, faces or necks exposed. Some rested their arms on work surfaces, and one lab worker had exposed facial hair.

Other problems involved poor maintenance procedures. Some parts of the NIH facility were cleaned with materials that could not kill fungal or bacterial spores, and some of the labs there rarely tested water quality or monitored airflow systems that are intended to prevent microbes from getting in or out of containment hoods.

In two 'clean rooms' intended to operate under strict contamination controls, FDA inspectors found insects in light fixtures.

“It’s troubling that an institution of NIH’s calibre had such serious deficiencies,” says Michael Carome, director of health research at Public Citizen, a non-profit watchdog organization in Washington DC. “These clearly could have put patients at risk of harm.”

Unexpected find

An employee at the NIH Clinical Center discovered the fungal contamination, Tabak says, but the agency does not know whether it was this person who registered the anonymous complaint with the FDA. The NIH does have a system for employees to report problems to supervisors, he adds.

In any case, Tabak says, “we're very grateful” to the person who contacted the FDA. “Their action led to the inspection that revealed the deficiencies.”

In the meantime, about 250 patients are enrolled in NIH clinical trials that use treatments supplied by the shuttered manufacturing facility. Tabak says that fewer than 50 of these people may need these drugs immediately to prevent their health from worsening.

If no alternative sources for the drugs can be found, NIH director Francis Collins will personally review each patient's case to determine whether medical need justifies giving the person a drug manufactured by the NIH lab.

The NIH has commissioned an external group of experts in manufacturing to investigate the cause of the situation. It would be premature, Tabak says, to comment on whether any individuals who worked at the pharmaceutical facility will be disciplined. The NIH says that it will file a corrective plan to the FDA by 19 June.

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