FDA cites quality problems at NY brain-imaging lab

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In this April 22, 2008 file photo, Erin Bialowas, standing, a PET/CT Technologist and Norm Amann, a business development director for Alliance Imaging, demonstrate a Position Emission Tomography or PET scan, during an open hose held inside their mobile unit at Eastern New Mexico Medical Center in Roswell, New Mexico. Columbia University's Kreitchman PET Center has halted some research after federal officials repeatedly complained about the quality of drugs being used on patients during PET scans. (AP/Roswell Daily Record, Mark Wilson, File)

(AP) -- A respected brain-imaging center run by Columbia University has halted some research after federal officials repeatedly complained that patients were getting drugs that failed purity tests.

The Food and Drug Administration found in a series of inspections that the center had failed to correct manufacturing problems in a lab that

makes experimental drugs injected into psychiatric patients to help capture images of brain activity.

In one warning letter, an FDA office in New York described problems dating back to at least 2004. It cited a litany of violations, including a failure to reject batches of medication that didn't pass required tests. The drugs were for patients undergoing a type of brain scan called positron emission tomography, or PET.

"We are concerned about the quality control systems and procedural problems that have allowed these significant deficiencies to occur," the FDA told the center in the letter, written in December 2008.

In a statement sent Saturday to The Associated Press, Columbia University Medical Center said it was restructuring the laboratory that produces the drugs for the Kreitchman PET Center.

It said an internal investigation, performed at the FDA's request, had found "no evidence of patient harm," but that all activities relying on the manufactured compounds had been suspended while reforms were undertaken.

"We acknowledge serious shortcomings of quality control in the manufacturing process and record keeping at this lab," said Dr. David Hirsh, the medical center's executive vice president for research.

"That is why we are fundamentally reorganizing the lab's management and operations in response to what the FDA told us. When manufacturing resumes under new leadership, it will meet the strictest standards and best practices for ensuring the quality of these materials," Hirsh said.

The problems at the imaging center and the halt in research were first

reported late Friday by The New York Times.

The PET Center remains in operation during the shakeup, and patients continue to receive treatment, Columbia said.

The problems at the center involved radiotracing drugs injected into a patient's brain to assist in capturing images used to study brain activity.

The drugs are not supposed to have any effect on the patient and they degrade quickly - so fast, in fact, that imaging centers must often manufacture them on the spot, rather than buy them from outside vendors.

The manufacturing process is strictly regulated by the FDA.

Dr. Alexander Neumeister, a psychiatrist with the molecular imaging program at the Mount Sinai School of Medicine, said PET centers across the country routinely test tracers for sterility and purity just minutes before they are injected, while the patient is lying on the table.

The tests, he said, turn up impurities about 1 percent to 3 percent of the time, and make it nearly impossible to unknowingly inject adulterated medications.

"You'd have to be an idiot," Neumeister said, adding that he was speaking generally about the testing procedure, rather than the situation at the Kreitchman PET Center. "It's like being pregnant - either you are, or you're not; it's very clear, there's no gray zone, no ambiguity."

If an impure tracer is used, any resulting scientific studies "are compromised," Neumeister said. It also might affect a person's health condition in unpredictable ways, like inducing allergies or worsening depression.

"It's not that you're killing a patient," he said, but, "you might be exposing your patient to various other levels of danger."

Among the problems at Columbia cited by the FDA were a failure to set up appropriate sterility tests, poor record keeping and lapses in training.

"If you're approved by the FDA to administer compounds that pass purity tests, and then inject substances that do not meet quality assurance regulations, you are breaking a sacred trust," said Dr. Nancy C. Andreasen, a former editor-in-chief of the American Journal of Psychiatry.

Andreasen, of the University of Iowa, an internationally known PET researcher, said the resulting studies are often used to determine dosages for treating patients in ordinary clinical settings. "And if a study is messed up, you could be overmedicating or undermedicating a patient," she said.