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Exclusive: US FDA finds control lapses at Moderna manufacturing plant

By **Patrick Wingrove**

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People pose with syringe with needle in front of displayed Moderna logo in this illustration taken, December 11, 2021. REUTERS/Dado Ruvic/Illustration/File Photo *Acquire Licensing Rights*

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Dec 15 (Reuters) - U.S. drug regulators in September found quality control lapses at Moderna's (MRNA.O) main factory including with equipment used to manufacture drug substance for its COVID-19 vaccine, according to the report obtained by Reuters via a Freedom of Information Act request.

The Sept. 11-21 inspection by the U.S. Food and Drug Administration took place at Moderna's facility in Norwood, Massachusetts, which is used to manufacture the company's COVID shot Spikevax and an experimental mRNA cancer vaccine being developed with Merck & Co (MRK.N).

The FDA report noted five separate observations, including that Moderna had released eight batches of "drug substance" - the active ingredient used to make mRNA vaccines - that was produced with equipment that had failed the company's cleaning verification tests.

The FDA did not say in the report if those batches were released to the public but identified the drug substance involved as being for the COVID vaccine. The agency declined to comment on the report.

Moderna in a statement said: "Upon receipt of the FDA's findings, Moderna immediately and comprehensively updated the specific procedures identified and is confident that the actions taken will be satisfactory to regulators."

The company described the inspection as routine and said the findings do not reflect any product quality or safety concerns, adding that its COVID-19 vaccines are safe and effective.

It said all product released by the company was tested and meets product specifications and international regulatory requirements.

Steven Lynn, a former head of the FDA's Office of Manufacturing and Product Quality who is now a regulatory compliance consultant, said using the drug substance in question was a serious matter but that it was unclear whether the batches were released to consumers.

The FDA also found in its report that Moderna did not have the right measures at its facility to ensure expired materials were not used to make vaccines and that airborne contaminates did not make it into any products.

Inspectors found more than 2,000 expired items in Moderna's warehouse and cold storage not held in a separate or defined location from other materials, according to the report. It also said it found materials were used beyond their expiration date.

“At face value, it appears multiple controls designed to prevent contamination were deficient,” said Lynn.

There is no evidence that compliance failures flagged in the report known as a Form 483 resulted in harm to people who took Moderna’s COVID shot, its only marketed product, or clinical trial participants for other mRNA vaccines the company is developing.

The FDA has not issued a recall of any Moderna vaccines, according to its recalls, market withdrawals, and safety alerts database.

A Form 483 is a type of agency report containing "observations" that FDA inspectors "deem to be objectionable."

In 2021, Japan suspended use of 1.63 million doses of Moderna’s COVID vaccine after

contaminates were found in some vials produced by Rovi (ROVI.MC), a contract manufacturer based in Spain. No manufacturing problems have previously been reported in any of Moderna's own facilities.

The drugmaker has also bought a manufacturing facility in Marlborough, Massachusetts, announced in May.

Moderna in September said it was in talks with its partners that fill vials and syringes with its COVID vaccine globally to downsize production and bring more manufacturing in-house as demand has waned.

The vaccine maker said it expects additional capacity from its new mRNA manufacturing facilities in the UK, Canada and Australia when completed in 2025.

Reporting by Patrick Wingrove; editing by Caroline Humer and Bill Berkrot

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