

FDA inspection found problems at factory making J&J vaccine

April 21 2021, by Linda A. Johnson



In this Wednesday, March 3, 2021 file photo, a pharmacist holds a vial of the Johnson & Johnson COVID-19 vaccine at a hospital in Bay Shore, N.Y. Janssen Pharmaceuticals is a division of Johnson & Johnson. On Wednesday, April 21, 2021, the Food and Drug Administration released a report saying the now-idle Emergent Biosciences factory where a key contractor hired to help make Johnson & Johnson's COVID-19 vaccine was dirty, didn't follow proper manufacturing procedures and had poorly trained staff, resulting in contamination of a batch of the vaccine. (AP Photo/Mark Lennihan)

The Baltimore factory contracted to make Johnson & Johnson's COVID-19 vaccine was dirty, didn't follow proper manufacturing procedures and had poorly trained staff, resulting in contamination of material that was going to be put in the shots, U.S. regulators said Wednesday.

The Food and Drug Administration released a statement and a [13-page report](#) detailing findings from its recent inspection of the now-idle Emergent BioSciences factory.

Agency inspectors said a batch of bulk drug substance for J&J's single-shot vaccine was contaminated with material used to make COVID-19 vaccines for another Emergent client, AstraZeneca. That batch, reportedly enough to make about 15 million J&J vaccine doses, had to be thrown out.

Other problems cited in the inspection report were peeling paint, black and brown residue on floors and walls in the factory, inadequate cleaning and employees not following procedures to prevent contamination.

Nothing made at the factory for J&J has been distributed, the FDA noted. The nearly 8 million doses of J&J vaccine given in the U.S. came from Europe.

Both Emergent and Johnson & Johnson said Wednesday that they are working to fix the problems as quickly as possible.

After quality problems surfaced late last month, J&J took control of the factory. The Biden administration now is working to move AstraZeneca vaccine manufacturing to another factory. AstraZeneca's vaccine is not yet authorized in the U.S.

The Baltimore factory halted all production late last week at the request of the FDA. The agency hasn't given emergency approval to the factory, which is needed before any vaccine material made there can be distributed.

All the bulk vaccine substance Emergent has made, plus early batches made there and then put in vials and packaged by other J&J contractors, are being stored and will undergo additional testing by the FDA, the agency said.

"We are doing everything we can to ensure that the COVID-19 vaccines that are given to the people of this nation have met the agency's high standards for quality, safety and effectiveness," the FDA said.

At the moment, use of the J&J vaccine is on hold in the U.S. as government health officials investigate its possible connection to very rare blood clots. Their decision on whether to allow the vaccine to be given could come Friday.

On Tuesday, the European Medicines Agency's safety committee said its review found the blood clots are a very rare side effect but that the J&J vaccine's benefits outweigh that risk.

Emergent, a little-known drug manufacturing contractor, was granted a major role in the Trump administration's response to the coronavirus. The company has been repeatedly cited by the FDA for problems ranging from poorly trained employees to cracked vials and mold around one of its facilities, according to records obtained by The Associated Press.

FDA inspectors started checking the Emergent factory in Baltimore on April 12 and finished their investigation on Tuesday.

The inspectors reviewed security camera footage that showed employees carrying unsealed bags of medical waste around in the factory, with the bags touching materials ready to be used to make vaccine batches. The footage also showed employees moving between manufacturing areas for the two vaccines without documenting whether they changed protective gowns and showered in between, as required.

The inspection report noted that Emergent didn't sufficiently investigate the contamination of the later-discarded J&J batch and didn't appear to have done any extra cleaning after the contamination was discovered.

"There is no assurance that other batches have not been subject to cross-contamination," the report stated.

It also noted that the factory had inadequate procedures for assuring that the vaccine substance met all quality and purity requirements.

It's unclear how long it will take the companies to resolve all the problems at the factory, known as Bayview.

J&J has pledged to provide 100 million doses for the U.S. by the end of May and 1 billion doses globally by the end of the year.

"Right now, we can't speculate on any potential impact this could have on the timing of our vaccine deliveries," J&J said in a statement.

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Citation: FDA inspection found problems at factory making J&J vaccine (2021, April 21)
retrieved 6 May 2024 from

<https://medicalxpress.com/news/2021-04-fda-problems-factory-jj-vaccine.html>

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