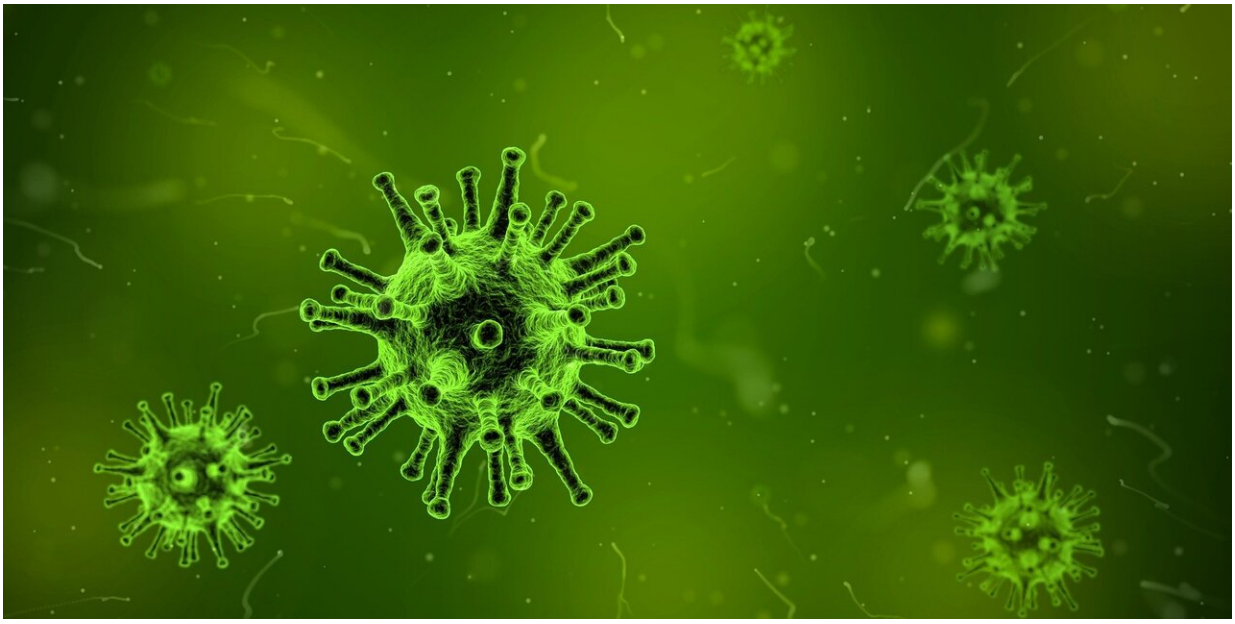
US to revise COVID vaccine guidance after allergic reactions

December 17 2020



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The US Food and Drug Administration (FDA) said Thursday it was working with Pfizer to revise a fact sheet for recipients of the Pfizer-BioNTech COVID-19 vaccine after two people had allergic reactions.

The two people, both health workers, were vaccinated in Alaska and one of them had a serious or "anaphylactic" reaction resulting in hospitalization.

Doran Fink, deputy director of the FDA's division of vaccines said: "All of these individuals were treated with appropriate medical intervention and thankfully, all are recovered or recovering.

"We anticipate that there may be additional reports, which we will rapidly investigate."

He added that US authorities, including the Centers for Disease Control and Prevention, were investigating the two cases and working with Britain to better understand two similar cases that occurred there.

"While the totality of data at this time continues to support vaccinations under the Pfizer EUA (emergency use authorization), without new restrictions, these cases underscore the need to remain vigilant during the early phase of the vaccination campaign," Fink said.

To this end, he said, "FDA is working with Pfizer to further revise the fact sheets and prescribing information for their vaccines to draw attention to CDC guidelines for post vaccination monitoring and management of immediate allergic reactions."

The revision will include the current warning for people who have a history of allergic reactions to the vaccine's ingredients to avoid getting the shot for now.

It will also include the warning that facilities where vaccines are being administered should ensure that medical treatment for managing serious allergic reactions is immediately available.

Fink added that should Moderna receive an emergency use authorization, it will come with similar warnings.

Both these vaccines are based on mRNA (messenger ribonucleic acid)

technology, which had never before been approved.