Despite impressive data, FDA's coronavirus vaccine reviews will take weeks, not days, official says

FDA official Peter Marks, M.D., Ph.D., said Americans can expect a "very open process" when it comes to COVID-19 vaccine reviews. (FDA)

As leading COVID-19 vaccines post positive phase 3 data and near FDA submissions, the agency official in charge of reviewing vaccines is emphasizing transparency and patience during the high-stakes process.

Americans should expect reviews to take weeks rather than days, Peter Marks, M.D., Ph.D., head of the FDA's Center for Biologics Evaluation and Research, told Business Insider. While the dire COVID-19 pandemic naturally creates urgency, Marks and his team "have to take the amount of time that we need to take," he said. The FDA is said to be discussing potential committee meetings for December 8 to 10, CNBC's Meg Tirrell reports.

"What we need here is confidence," Marks told BI. "Everything that we are trying to do here, this is all about ensuring the public re-develops the kind of trust they once had in vaccines."

Toward that goal, as the leading candidates move to the regulatory stage, Americans can expect a "very open process," he said.

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His remarks come as Pfizer and its partner BioNTech finished their large phase 3 trial, reporting 95% efficacy and no serious safety concerns for their mRNA vaccine. Each vaccine that comes under review at the agency will have a separate public hearing to closely scrutinize the data, officials have said.

Following their trial, Pfizer and BioNTech plan to seek an emergency use authorization "within days."

As the FDA's top vaccines official, Marks has made headlines before during the COVID-19 pandemic. He's previously said he'd retire if any outsiders tried to exert force on his organization's review processes, and again made that commitment in his BI interview. Previously, Marks told Fierce Pharma it's his job to allow "the process to take place ... free of distractions from factors that aren't related to quality, safety or efficacy of the vaccine."

In addition to the FDA's rigorous review process, the CDC's Advisory Committee on Immunization Practices typically takes a deep look into vaccine data and makes recommendations about who should receive vaccines.

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Pfizer isn't alone in nearing a potential EUA submission. Moderna this week revealed its vaccine was 94.5% effective in an interim analysis. The company intends to submit the data to the FDA "in the coming weeks." Aside from those programs, Johnson & Johnson, AstraZeneca and Novavax are in phase 3, and a host of other players are in earlier stages of testing.