

With concerns rising that Trump was conspiring to end run FDA vaccine standards, White House reverses decision to block release after the agency ignored the president and published them anyway

The White House on [October 6] approved [tough new standards](#) for coronavirus vaccines after weeks of delay, but only after the Food and Drug Administration unilaterally published the guidelines on its website as part of its briefing materials for outside vaccine advisers.

The standards, which would be used for an emergency authorization of a vaccine, are the same ones the agency proposed weeks ago as part of an effort to boost public confidence in an eventual vaccine.

In many cases, they are close to the standards for a full approval of the vaccine. But the White House, worried the criteria would delay authorization of a vaccine, presumably beyond the Nov. 3 election, sat on the guidance.

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On [October 6], FDA officials circumvented the White House by publishing the criteria online as part of a briefing package for its vaccine advisory committee, which is meeting Oct. 22. Shortly afterward, the White House cleared publication of the standards, according to a senior administration official, who spoke on the condition of anonymity because the person was not authorized to talk publicly.

"Being open and clear about the circumstances under which the issuance of an emergency use authorization for a COVID-19 vaccine would be appropriate is critical to building public confidence and ensuring the use of COVID-19 vaccines once available," Peter Marks, director of the Center for Biologics Evaluation and Research, which oversees vaccines, said in a statement.

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