

## FDA Scraps Trump-Era Leeway For Lab Test Authorizations

By Adam Lidgett

*Law360 (November 15, 2021, 8:22 PM EST)* -- Federal regulators have dumped a Trump-era decision that said the U.S. Food and Drug Administration didn't have to require premarket review of lab-developed COVID-19 tests.

The U.S. Department of Health and Human Services on Monday said it was rescinding a policy from August 2020 that stated the FDA would not require premarket review of any laboratory-developed tests for COVID-19.

That change would make sure "that COVID-19 tests are accurate and reliable," the FDA said in a release.

"In addition to vaccination efforts, testing remains a cornerstone of the national response to the pandemic and plays a central role in helping Americans get back to work, school and other important activities, particularly as the holiday season approaches," Jeff Shuren, the director of the Center for Devices and Radiological Health, said.

"The FDA remains committed to helping to increase the availability of tests that will have the biggest impact on the nation's ongoing COVID-19 testing needs, such as at-home and point-of-care diagnostic tests that can be produced in high volumes."

The FDA said that now it will generally expect that COVID-19 tests will have a greenlight, such as an emergency use authorization or traditional marketing authorization before going out.

Some test makers were giving out tests before an emergency use authorization, which was a way to hasten test availability, the FDA said.

But that "led to some poorly performing tests being offered prior to FDA review," the FDA said, while noting that the policies at issue were not for at-home tests.

"This withdrawal is a long time coming, but you can tell from how thoughtful and thorough the guidance is that it took a long time to develop," Stacy Cline Amin, co-leader of Morrison & Foerster's FDA regulatory and compliance group, said to Law360 in a statement. "Looking beyond COVID-19, I anticipate that both FDA and the industry will pivot now to focus on legislation that will provide long-term certainty and clarity to test developers."