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FDA's Shuren: 'Senior-Level Folks' Will Take Part In New Inspectional Affairs Council

by Shawn M. Schmitt

US FDA device center director Jeff Shuren on 6 May shed a tiny bit of light on the agency's newly announced – but not defined – Inspectional Affairs Council.

The director of the US Food and Drug Administration's device center was tight-lipped on 6 May about the agency's plans to launch a new Inspectional Affairs Council.

"Some of the specifics are still being worked out, but it's anticipated we will have senior-level folks from across the agency participating" in the council, Jeff Shuren said at MedCon 2021, hosted by the FDA and Cincinnati's Xavier University.

In announcing the release of a report on inspectional oversight on 5 May, the FDA said it was "establishing an agency-wide FDA Inspectional Affairs Council that will plan and coordinate inspectional activities," but gave no specifics. (*See sidebar story.*)

Shuren didn't offer insight into who at the agency or what FDA office would oversee the forthcoming council, but he did say it's a "wonderful opportunity."

"I continue to see the silver lining out of COVID. It's really kind of pushed us to do a lot of things in new ways, and we're taking advantage of that," he said. "Creation of this council – and the thinking around inspections and related activities – is really an outgrowth of those experiences."

At Best, FDA Will Carry Out Only Half Of Domestic Surveillance Inspections In FY 2021, Report Says

By Shawn M. Schmitt

05 May 2021

A 5 May report from the US FDA says that even under the most favorable COVID-19 conditions the agency's inspections of makers

The agency's Office of Regulatory Affairs – which conducts all of the FDA's field activities – already plans and coordinates inspections, so it's unclear exactly how the new council would complement those efforts.

Meanwhile, the FDA's 5 May *report* further said the agency is planning what it calls a "multiyear modernization effort" to bolster its regulatory oversight.

of medical and tobacco products will likely be cut in half this fiscal year. The FDA also announced it will launch an agency-wide Inspectional Affairs Council to "plan and coordinate inspectional activities."

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The initiative will "further transform our data enterprise platforms and cross-program interoperability infrastructure to better support innovation related to our regulatory oversight role, including remote approaches," the agency said.

"This modernization effort will include a review of approaches to regulatory oversight using next-generation assessment technologies and improvements, as well as a review of available authorities for any potential legislative proposals."