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Don’t Call Them Inspections: EUA Holders Shouldn’t Be Surprised If FDA Shows Up To Investigate

by Shawn M. Schmitt

The US FDA is reminding companies with emergency use authorizations for COVID-19 products that the agency has the authority to conduct investigations (but not inspections) of their manufacturing facilities.

The US Food and Drug Administration is reminding holders of emergency use authorizations (EUAs) that they shouldn’t be surprised if an agency investigator knocks on their facility door for a look-see.

“While EUAs have been around for some time, an unparalleled number of EUAs were being considered related to the COVID-19 countermeasures,” said Elizabeth Miller, assistant commissioner for medical products and tobacco operations within the FDA’s Office of Regulatory Affairs. The ORA is the lead office for all of the agency’s field activities.

“Recognizing the need to create transparent insight into our engagement with industry on [EUAs], within [the ORA] we developed a new Field Management Directive, *FMD-153*, which outlines the process that investigations of facilities manufacturing potential EUA products could be assessed,” Miller said on 16 November at the WCG-FDAnews 16th Annual FDA Inspections Summit.

The agency in January rolled out FMD-153, “Investigations of Facilities engaged in the Manufacturing, Packaging, Labeling, and Testing of Medical Products that may be subject to an Emergency Use Authorization.”

“The Field Management Directive is the information-gathering activity to ensure the potential facility intended to manufacture the EUA product is capable of manufacturing, packaging, labeling or testing the product intended for use in a public health emergency,” Miller said. “The

purpose of the investigation is to ensure the public health goal of providing emergency use access to safe, effective and quality novel critical therapies and diagnostics."

> *"These investigational activities allow the agency to directly observe operations at manufacturers of COVID-19" products. – Elizabeth Miller*

FMD-153 says it aims to provide "criteria and instructions to [FDA] investigators when conducting an investigation" of a company with an EUA product. Investigations must be requested by one of the agency's various commodity centers – the ORA doesn't investigate unless it's asked.

"Investigations conducted under this FMD are intended to appropriately facilitate access to certain medical products that may be urgently needed for use by gathering information about the facility, the manufacturing process and the ability to maintain the quality and the consistency of the subject product," Miller said. "These investigational activities allow the agency to directly observe operations at manufacturers of COVID-19" products.

She went on: "The FMD describes the responsibilities and the procedures, and outlines how we will conduct investigations in these situations, rather than inspections."

An investigation under FMD-153 has a similar framework as a typical surveillance inspection, including a pre-announcement to firms and the issuance of an FDA-482 form by an investigator upon entering a facility. The 482 is given to the most responsible person on-site at the company. (Foreign firms aren't given an FDA-482.)

Next, "the investigator(s) will collect information and records regarding the firm's operational activities, including those that are in various stages of development," FMD-153 says, noting that

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The pandemic caused the US FDA's Office of Regulatory Affairs to consider ways it can be more nimble in its inspectional activities, including launching an agency-wide council to tackle and solve inspection-related issues,

"investigator(s) should discuss FDA concerns regarding the facility, its operations, and/or the medical product(s) that may be subject to an EUA, with the facility's management during the course of the investigation."

the ORA's Elizabeth Miller says.

Read the full article here

And just like an inspection, an EUA-related investigation includes a close-out meeting where investigators can share overall findings with the company. The close-out may be conducted remotely.

"Feedback is provided to the firm to optimize their compliance with CGMP [Current Good Manufacturing Practice] regulations and to help ensure that patients and their health care providers have access to safe and effective medical countermeasures," Miller said.

FMD-153 further explains: "During the close-out meeting, the investigator(s) will advise the firm that they should promptly respond to any unresolved concerns in writing to the applicable program office."