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CLIENT ALERT

FDA Warning Letter Sends Pointed Message to Industry about EUAs and Compliance

October 9, 2020

On October 7, 2020, the U.S. Food and Drug Administration ("FDA") issued a warning letter to Battelle Memorial Institute ("Battelle") for failing to adhere to Emergency Use Authorization ("EUA") requirements for its N95 mask decontamination units. Battelle's decontamination system, designed to sanitize N95 masks for healthcare professionals and thereby mitigate the shortage of N95 masks, was granted an EUA on March 28, 2020.

The Agency has eased its ordinarily stringent regulatory approval process for certain drugs and medical devices, opting instead to issue EUAs for products urgently needed during the pandemic. Companies granted emergency authorization may distribute products that are not formally FDA-approved subject to their ongoing adherence to conditions set forth in the applicable EUA. Such conditions almost always include adverse event reporting requirements, which the FDA views as a vital surveillance tool used to monitor the performance of these products and detect potential safety issues.

Per the Battelle EUA, the company must "have a process in place to report adverse events of which they become aware to FDA related to the Battelle Decontamination System . . . in accordance with 21 CFR Part 803." The FDA has identified that reportable events include:

- allergic reactions;
- evidence that a decontaminated respirator is unable to perform its essential function and its therapeutic effect is compromised, such as a shrunken or misshaped decontaminated respirator;
- infections in respirator wearers, healthcare personnel, or respirator decontamination staff; and
- malfunctions of the generator used to decontaminate the respirators.

On August 7, 2020, the FDA sent the company a letter requesting information about Battelle's adverse event reporting process and, ultimately, determined that Battelle's reporting process was deficient.

In the October 7 warning letter, the FDA outlined the various ways in which Battelle had failed to meet EUA conditions, and demanded that the company "take immediate action to correct the violations cited in [the] letter." The FDA also noted that while it had become aware of reportable events that may have been relevant to Battelle's products, the company had not submitted a single adverse event report. Battelle was given 15 days in which to submit a detailed plan about how it would correct its violations.

In a press release, Dr. Binita Ashar, director of the Office of Surgical and Infection Control Devices in the Center for Devices and Radiological Health, stated, "[i]t is critical that manufacturers have an effective process in place for reporting adverse events related to the use of authorized systems for decontaminating respirators. When there is an inadequate adverse event reporting process, the ability to detect problems and address them in order to assure the safety and performance of decontaminated

respirators is compromised." She cautioned, "[w]e will hold companies accountable if they fail to fulfill their regulatory obligations."

These actions serve as a reminder that EUAs contain their own set of requirements that must be followed, including reporting and monitoring obligations. The ability to monitor and report adverse events are especially important given the circumstances of the emergency and the need to ensure the safety and effectiveness of unapproved products. The FDA has demonstrated that it is ready and willing to pursue enforcement actions against companies that do not comply.

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