Public Health Emergency Set to End on May 11.

This does not affect the LUISA ventilator EUA.

With the announcement of the COVID-19 public health emergency (PHE) expiring on May 11, 2023, we wanted to provide some information on the differences between the PHE and Emergency Use Authorization (EUA) medical devices and what the expiration of the PHE means for these devices:

Question: The Public Health Emergency (PHE) for COVID-19 is scheduled to expire on May 11, 2023[1], what happens to COVID-19 Emergency Use Authorizations (EUA's) issued by the FDA on May 11, 2023?

Answer: **There is no impact to EUA's issued by the FDA when the PHE for COVID-19 expires. Specifically, the LUISA Ventilator EUA does not expire on May 11, 2023.** EUA's are issued under a separate declaration from the Secretary of Health and Human Services (HHS). Per the FDA, EUA's are "distinct from, and not dependent on, an HHS PPE declaration under section 319 of the PHS Act, and therefore, an EUA may remain in effect beyond the duration of the section 319 PHE declaration…."[2]

Question: When will FDA begin terminating existing EUA's, specifically those related to ventilators?

Answer: FDA has not announced any timeframe related to terminating existing ventilator EUA's. However, FDA has issued a draft guidance document related to transitioning from EUA's. Based on the draft guidance, FDA intends to allow ample transition time for all stakeholders. This would include at least 180 days after publishing notice of EUA termination in the Federal Register[3].

Question: What happens when an EUA is finally terminated by FDA, after the 180-day transition period?

Answer: According to draft FDA Guidance, the FDA does not intend to object to continued distribution of EUA devices so long as the manufacturer has submitted a marketing submission (such as a 510(k)) to the FDA which has been accepted by FDA prior to the EUA termination date, and no final decision on that submission has been reached. In addition, FDA does not intend to request withdrawal of EUA devices which are already being used on patients.[3]

A 510(k) submission for the LUISA ventilator has been accepted by the FDA and is pending for 510(k) clearance. The assigned 510(k) number is K221316. The planned indications for use under the 510k include both adult and pediatric populations, as well as invasive or non-invasive ventilation. Once 510(k) cleared, Movair believes the most likely scenario to bring EUA devices into compliance with the 510(k) will involve performing a field firmware update and providing updated labeling for EUA devices.

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[1] Statement of Administration Policy, January 30, 2023. Executive Office of the President.

[2] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends

[3] Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, available at https://www.fda.gov/media/155039/download.