Non-NIOSH Approved Respirator EUA FAQ

1. Do filtering face-piece respirators (FFRs) not approved by the National Institutes of Occupational Safety and Health (NIOSH), provide the same protection as NIOSH-approved respirators?

As mentioned in CDC's strategies for optimizing respirator supply (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html), other countries approve respirators according to standards. These devices are evaluated using methods similar to those used by NIOSH, and are still expected to provide adequate protection for healthcare personnel, given shortages of FFRs resulting from the COVID-19 pandemic. Under these circumstances, FDA believes these devices may serve as suitable alternatives for personal respiratory protection during this period of shortage caused by the COVID-19 pandemic.

2. Can I import respirators to the US if the standards or approval mechanism from my country is not listed as criteria for eligibility under this Emergency Use Authorization (EUA)?

Respirator manufacturers whose countries' standards or approval mechanism are not included under this EUA should submit a separate EUA request if they would like to import their product into the US for use in healthcare settings. General background on EUAs can be found here (/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities). Requests for this particular EUA should be made to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov (mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov) with the text "Non-NIOSH-Approved Respirator" in the subject line and include:

A. General information such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any) in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region).

B. A copy of the product labeling.

C. Whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number, if available).

D. Whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes or an equivalent quality system and the manufacturer or importer has documentation of such.

E. Description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate

3. If my respirators are authorized for use under the EUA, what do I need to do to import them? Who do I contact if my authorized respirator has import issues?

Import information can be found on the Custom and Border Patrol website, CSMS Message #42124872 (https://content.govdelivery.com/bulletins/gd/USDHSCBP-282c648?wgt_ref=USDHSCBP_WIDGET_2?utm_source=csms.cbp.gov&utm_medium=csms.cbp.gov&utm_term=undefined&utm_content=undefined&utm_campaign=(not%20set)&gclid=undefined&dclid=undefined&GAID=1278996374.1567630590) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Please contact COVID19FDAIMPORTINQUIRIES@fda.hhs.gov (mailto:COVID19FDAIMPORTINQUIRIES@fda.hhs.gov) or 301-796-0356 to resolve entry issues for shipments.