NIOSH Conformity Assessment Letter to Manufacturers

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June 2020

Subject: Clarification about U.S. Food and Drug Administration (FDA) Emergency Use Authorizations (EUA) Applicable to Existing NIOSH Respirator Approval Holders

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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In response to the nation's effort to control the spread of the coronavirus disease 2019 (COVID-19) outbreak, the U.S. Food and Drug Administration (FDA), Centers for Disease Control Prevention (CDC), and National Institute for Occupational Safety and Health (NIOSH) are working together to address respiratory protection needs.

The NIOSH Respirator Approval Program is seeking to clarify the FDA's Emergency Use Authorization (EUA), dated March 28, 2020, for existing NIOSH Approval Holders. The EUA of interest is listed as *NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to COVID-19 Public Health Emergency*. **All NIOSH-approved air-purifying particulate respirators produced domestically and internationally (including those NIOSH-approved N95 filtering facepiece respirators (FFRs) produced in China) are covered under this EUA.** However, the EUA provides information for NIOSH Approval Holders intending to withdraw authorized models from coverage under the EUA.

On May 7, 2020 the FDA updated a separate EUA that **IS SPECIFIC** to KN95 masks, **NOT** NIOSH-approved N95 FFRs. This EUA is further identified by the memorandum salutation, *To: Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators; first issued on April 3, 2020, Imported China.* **FDA actions to delist KN95 manufactures from inclusion in this EUA (Appendix A) do not impact the NIOSH-approved N95 FFRs and other NIOSH-approved respirators covered under the above referenced March 28, 2020 EUA.** Supplemental information regarding KN95 respirators is provided, below.

Supplemental Information regarding KN95 masks

The standard against which respirators are evaluated for approval as KN95 respirators is **not** one used by NIOSH; therefore, NIOSH does not acknowledge "KN95" as a level of approved respiratory protection.

To be added back to Appendix A of the May 7, 2020 revised FDA EUA (Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators; April 3, 2020, Imported China), the applicant **must follow** the guidance in the FDA EUA. https://www.fda.gov/media/136664/download

Do not contact NIOSH if you are a distributor or importer of KN95 masks manufactured in China.

NIOSH is supporting FDA by offering limited testing of KN95 devices. KN95 manufacturers - do NOT contact NIOSH directly for testing. The NIOSH testing assessment must be coordinated between the KN95 manufacturer and the FDA.

Criteria 3 of the **revised** EUA states:

*It was previously listed in Appendix A under the April 3, 2020 letter of authorization as an authorized respirator because it demonstrated acceptable performance to applicable standards as documented by test reports, has had particulate filtration efficiency assessed by NIOSH using a modified version of NIOSH's Standard Test Procedure (STP) TEB-APR-STP-0059 within 45 calendar days of the date of issuance of this EUA, and has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent.**

* *FDA will sample respirators from already imported lots of respirators under this criterion. If a manufacturer has not shipped respirators to the United States at the time this EUA is reissued, FDA will work with a manufacturer who is eligible for this criterion in order to sample respirators once they arrive at a US port of entry.*

Therefore, the KN95 manufacturer must work with the FDA in order to be listed on Appendix A. The FDA will coordinate the testing assessment with NIOSH.