In a June 6 Letter of Authorization (LoA), the U.S. Food and Drug Administration (FDA) reissued its March 28 LoA to revise emergency use authorization (EUA) eligibility criteria for imported, non-National Institute for Occupational Safety and Health (NIOSH)-approved disposable filtering facepiece respirators (FFR or respirator). Exhibit 1 lists authorized respirators.

As a result of the revision, imported, non-NIOSH approved respirators not manufactured in China can be authorized by meeting one of three criteria:

1. Disposable FFRs that have been designed, evaluated, and validated to meet a given performance standard and have corresponding acceptable product classifications as outlined in Table 1 of the EUA.

2. Disposable FFRs that conform to Personal Protective Equipment (PPE) Directive 89/686 EEC (for those placed in distribution prior to April 21, 2019) or that conform to PPE Regulation (European Union (EU)) 2016/425 (for those placed in
distribution after April 21, 2019), as evidenced by a CE Mark, and the CE Mark as been authenticated and verified by the FDA.

3. Disposable FFRs that are manufactured by entities that hold one or more NIOSH approvals, that have been verified by the FDA, for FFRs, and that are produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country.

If FDA confirms eligibility, FDA will add the respirator to the list of authorized respirators in Exhibit 1. Authorized respirators are also subject to random sampling and filtration efficiency performance testing upon importation into the United States.

In addition to changes regarding eligibility criteria, the June 6 LoA removed decontaminated respirators with exhalation valves from the EUA. The June 6 LoA also added requirements related to advertising and promotion and the requirement of samples for testing when requested by the FDA. For a full list of the requirements for authorized respirators, please reference the full June 6 LoA.

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