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FDA Policy for Face Masks and Respirators in COVID-19 (2020)

US Food and Drug Administration (FDA)

This is a quick summary of the guidelines without analysis or commentary. For more information, go directly to the guidelines by clicking the link in the reference.

March 27, 2020

The guidelines on policy for face masks and respirators during the COVID-19 public health emergency were released in March 2020 by the US Food and Drug Administration (FDA).[1]

Face Masks and N95 Respirators Not Intended for a Medical Purpose

Face masks and N95 respirators are devices when they are intended for a medical purpose (eg, preventing transmission of infectious disease, including COVID-19). They are not devices when they are intended for a nonmedical purpose, and in such cases, FDA device marketing authorization is not required for them.

When considering whether face masks and respirators are intended for a medical purpose, among other considerations, FDA will look at the following:

- Whether they are labeled or otherwise intended for use by a healthcare professional
- Whether they are labeled or otherwise for use in a healthcare facility or environment
- Whether they include any drugs, biologics, or antimicrobial/antiviral agents

Face Masks Intended for a Medical Purpose That Are Not Intended to Provide Liquid Barrier Protection

In general, FDA recommends that healthcare providers follow current Centers for Disease Control and Prevention (CDC) guidance regarding the use of personal protective equipment (PPE) during the COVID-19 outbreak.

For the duration of the public health emergency, FDA does not intend to object to the distribution and use of face masks (not including respirators) that are intended for a medical purpose (whether used by medical personnel or by the general public), without compliance with regulatory requirements, in instances where the face mask does not create an undue risk in light of the public health emergency.

FDA currently believes that such devices would not create an undue risk in the following cases:

- The product's labeling accurately describes the product as a face mask (as opposed to a surgical mask or filtering facepiece respirator [FFR]) and includes a list of the body-contacting materials (which include no drugs or biologics).
- The product's labeling makes recommendations that would sufficiently reduce the risk of use—for example, recommendations against use in any surgical setting or a setting where significant exposure to liquid, bodily fluids, or other hazardous fluids may be expected; use in a clinical setting with a high risk of infection through inhalation exposure; and use in the presence of a high-intensity heat source or flammable gas.
- The product is not intended for any use that would create an undue risk—for example, the labeling does not include uses for antimicrobial/antiviral protection or related uses or uses for infection prevention/reduction or related uses and does not include particulate filtration claims.

Surgical Masks Intended to Provide Liquid Barrier Protection

For the duration of the declared public health emergency, FDA does not intend to object to the distribution and use of surgical masks without prior submission of a premarket notification in instances where the surgical masks do not create an undue risk in light of the public health emergency.

FDA currently believes that such devices would not create an undue risk in the following cases:

- The product meets fluid resistance testing (liquid barrier performance) requirements in a manner consistent with standard methods.

- The product meets standard class I or class II flammability requirements (unless labeled with a recommendation against use in the presence of high-intensity heat sources or flammable gas).
- The product's labeling accurately describes the product as a surgical mask and includes a list of the body-contacting materials (which include no drugs or biologics).
- The product is not intended for any use that would create an undue risk—for example, the labeling does not include uses for antimicrobial/antiviral protection or related uses or uses for infection prevention/reduction or related uses and does not include particulate filtration claims.

Intended Approach for Emergency Use Authorizations (EUAs) for Masks and Respirators

EUAs for reprocessing of FFRs

To facilitate safe reuse and conservation of PPE for the duration of the emergency, FDA is interested in interacting with manufacturers on reprocessing of otherwise disposable N95 particulate-filtering facepiece respirators (and other FFRs) to facilitate marketing authorization through an EUA. Firms should contact FDA (CDRH-COVID19-SurgicalMasks@fda.hhs.gov) and provide the following information:

- Description of the process for disinfection/reprocessing controls
- Validation of bioburden reduction/disinfection
- Description of chain of custody and safeguards to prevent inadvertent exposure
- Material compatibility
- Filtration performance
- Fit test data
- Copy of the reprocessed device product labeling

EUAs for face masks intended for a medical purpose, surgical face masks, and N95 respirators

FDA has already issued EUAs that authorize certain N95 FFRs for use in healthcare settings by healthcare personnel in order to increase availability of these devices to frontline personnel. FDA is interested in interacting with manufacturers on additional device-specific EUAs. This may include both manufacturers of devices not currently marketed in the US and manufacturers who have not previously manufactured masks or respirators but have the capability to increase the supply of these devices.

For current face mask and respirator manufacturers whose product(s) are not currently marketed in the US, FDA recommends providing the following information:

- General information (eg, contact information, general information about the device)
- Copy of the product labeling.
- Any current marketing authorization (if any) for the device in another regulatory jurisdiction
- Whether the device is manufactured in compliance with an appropriate quality system and whether documentation of such is available
- Any testing conducted on the device, including any standards met

Face mask manufacturers who have not previously been engaged in medical device manufacturing but with capabilities to increase supply of these devices should send an email to FDA (CDRH-COVID19-SurgicalMasks@fda.hhs.gov) and describe their proposed approach.

For any face mask or filtering facepiece respirator (including N95 respirators) issued an EUA, FDA will include appropriate conditions of authorization in accordance with section 564 of the FD&C Act.

For more information, please go to Coronavirus Disease 2019 (COVID-19).

For more Clinical Practice Guidelines, please go to Guidelines.

References

1. Enforcement policy for face masks and respirators during the coronavirus disease (COVID-19) public health emergency: guidance for industry and Food and Drug Administration staff. US Food and Drug Administration. March 2020; Accessed: March 26, 2020. Available at: https://www.fda.gov/media/136449/download.

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