Life Sciences

COVID-19: Clearing Up Confusion Regarding Emergency Use Authorization for N95 Respirators and Face Masks — Part 2

As the COVID-19 pandemic continues to unfold, physicians, nurses, and other caregivers nationwide are facing a shortage of N95 respirators, masks, and other personal protection equipment (PPE), putting the safety of patients and clinicians at risk.

The U.S. Food and Drug Administration (FDA) is sprinting a marathon when it comes to releasing guidance documents and issuing Emergency Use Authorizations (EUA).

On April 6, 2020, the FDA held a **Webinar** titled, "Enforcement Policy for Personal Protective Equipment (PPE) During COVID-19: Immediately in Effect Guidances."

Here are the key findings

What is Emergency Use Authorization?

Emergency Use Authorization (EUA) helps get promising medical products to patients as quickly as possible by allowing unapproved medical products or unapproved uses of approved medical products to be used in an emergency when there are no adequate, approved, and available alternatives:

- Requires FDA review of performance, safety and labeling
- Allows devices not FDA-cleared or approved to be marketed in the U.S.
- Waives FDA Current Goods Manufacturing Practices and the quality system requirements, Title 21 Code of Federal Regulations (CFR) Part 820 (design, manufacture, packaging, labeling, storage, and distribution)
- In effect for the duration of the national emergency

Face Masks and Respirators to EUA or not to EUA

1. Face shields and masks

The FDA does not intend to object to distribution and use (including importation) of the devices below without compliance with certain regulatory requirements, including 510(k), registration and listing, and quality system regulation requirements, when the devices are tested and labeled consistent with the **enforcement policy**.

- Face shields intended for a medical purpose
- Face masks intended for a medical purpose that are NOT intended to provide liquid barrier protection
- Surgical masks intended to provide liquid barrier protection

2. N95 respirators

When FDA-cleared or National Institute for Occupational Safety and Health (NIOSH)-approved N95 respirators are not available, the FDA does not intend to object to the distribution (including importation) and use of respirators identified in the Centers for Disease Control and Prevention recommendations: **Strategies for Optimizing the Supply of N95 Respirators Importers**. This is because if the FDA cannot confirm the authenticity of these respirators, the FDA recommends that importers take appropriate steps to verify the authenticity of the products they import.

The documents below highlight how to receive EUA for an N95	**Requests for N95 respirator EUA should include**
• **NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency** • **Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China** • **Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators EUAs for Face Masks Intended for a Medical Purpose, Surgical Face Masks and N95 Respirators**	• General information. • Product labeling. • Whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number). • Whether the device is manufactured in compliance with 21 CFR Part 820, ISO 13485 or an equivalent quality system. • Description of testing conducted on the device. Send requests to **CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov**.

EUA Requests for Decontamination of Face Masks and Respirators

Detailed information on what to include in your EUA request is available in Section VI of the **Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency**.

Requests should go to: **CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov**.

Requests should include:

- Critical cycle parameters.
- Validation of disinfection (bioburden reduction).
- Chain of custody and safeguards to prevent inadvertent exposure.
- Material compatibility.
- Any applicable filtration performance.
- Fit test data.
- Labeling (decontaminated device).

Additional Policy Intended to Expand the Availability of PPE

Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency

Gowns and Other Apparel

The FDA does not intend to object to distribution and use (including importation) of the devices below without compliance with certain regulatory requirements, including 510(k), registration and listing, and quality system regulation requirements when the devices are tested and labeled consistent with the enforcement policy.

- Non-surgical gowns and minimal-to-low barrier protection surgical apparel
- Moderate-to-high barrier protection surgical gowns

Patient Examination Glove

The FDA does not intend to object to distribution and use (including importation) of the devices below without compliance with certain regulatory requirements, including 510(k), registration and listing, and quality system regulation requirements when the devices are tested and labeled consistent with the enforcement policy.

- Patient examination gloves
- Surgeon's gloves enforcement policy

Resources

Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency

Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency

Battelle Decontamination System EUA

NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency

Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

EUA Clarification Letter on Respirators

Non-NIOSH Approved Respirator EUA FAQ

Fact Sheet for Healthcare Personnel

Instructions for Healthcare Facilities

Instructions for Healthcare Personnel

Strategies for Optimizing the Supply of N95 Respirators

Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers

Medical Glove Conservation Strategies: Letter to Health Care Providers

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