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Enforcement Policy for Personal Protective Equipment (PPE) During COVID-19: Immediately in Effect Guidances

Office of Health Technology 4: Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

March 6, 2020

Agenda

- Introduction
- Devices
  - Face Mask and Respirator Policies
  - Emergency Use Authorizations (EUAs) for Face Masks, Surgical Masks, and N95 Respirators
  - EUAs for Decontamination of Face Masks and Respirators
  - Gowns
  - Gloves
- Resources
- Questions

Objectives

- To describe the FDA's enforcement policies for face masks, respirators, gowns, and gloves.

- To describe the FDA's Emergency Use Authorizations for non-NIOSH-approved disposable filtering facepiece respirators, NIOSH-approved air purifying respirators, and N95 respirator decontamination.

Background

- Most personal protective equipment, such as surgical gowns, face masks, and respirators are regulated by the FDA.
- The COVID-19 pandemic presents significant challenges to the availability of personal protective equipment in health care facilities.
- The FDA has authorized the emergency use of certain personal protective equipment and issued guidance on enforcement policies that together establish maximum regulatory flexibility to help facilitate access to critical medical supplies.

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CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Face Mask and Respirator Policies

Cynthia J. Chang, Ph.D.

Director

Division of Infection Control & Plastic and Reconstructive Surgery Devices

Enforcement Policy Guidance

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

- Achieve maximum regulatory flexibility while assuring products are appropriate for their use.
- Discretion as to certain other FDA requirements
- In effect for the duration of the national emergency

Scope

- Face masks, face shields, and N95 respirators not intended for a medical purpose
- Face masks intended for a medical purpose that are not intended to provide liquid barrier protection
- Face shields intended for a medical purpose
- Surgical masks intended to provide liquid barrier protection
- Alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available

Face Mask

A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels.

N95 Respirator

A disposable half-mask filtering facepiece respirator (FFR) that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. An N95 FFR used in a health care setting is regulated by the FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification or is a class II cleared device.

Face Shield

A face shield is a device used to protect the user's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. Generally, a face shield is situated at the crown of the head and is constructed with plastic to cover the user’s eyes and face.

Surgical mask

A mask that covers the user’s nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests, CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.

Enforcement Policy

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.

Devices

- 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

Alternatives When FDA-Cleared or NIOSH-Approved N95 Respirators are not Available

When FDA-cleared or 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 CDC recommendations: Strategies for Optimizing the Supply of N95 Respirators

Importers Note: For non-EUA products

- Because 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.

Emergency Use Authorizations (EUAs) for Face Masks, Surgical Masks, and N95 Respirators

Cynthia J. Chang, Ph.D.

Director

Division of Infection Control & Plastic and Reconstructive Surgery Devices

Emergency Use Authorization

- 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 cGMP and the quality system requirements, 21 CFR Part 820 (design, manufacture, packaging, labeling, storage, and distribution)
- In effect for the duration of the national emergency

EUAs for Face Masks Intended for a Medical Purpose, Surgical Face Masks and N95 Respirators

Detailed information on what to include in your EUA request is available in:

- 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

EUA Requests

Requests should include:

- 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

EUAs for Decontamination of Face Masks and Respirators

Clarence Murray III, Ph.D.
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EUAs 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

Submit requests to:

CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov

EUAs for Decontamination of Face Masks and Respirators

Requests should include:

1. Critical Cycle Parameters
2. Validation of disinfection (bioburden reduction)
3. Chain of custody and safeguards to prevent inadvertent exposure
4. Material compatibility
5. Any applicable filtration performance
6. Fit test data
7. Labeling (decontaminated device)

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Gowns

BiFeng Qian, Ph.D.
Scientific Reviewer

Enforcement Policy Guidance

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

- Achieves maximum regulatory flexibility while assuring the product is appropriate for its use
- In effect for the duration of the national emergency

Scope

- Gowns and other apparel are products intended to protect the user from the transfer of materials in the wearer's environment.
- The classification regulation and associated product codes for FDA-regulated gowns and other apparel covered by the guidance are listed in the resources section of this presentation
- FDA-regulated gowns and other apparel that are covered by the guidance are listed in the resources section of this presentation
- This guidance does not apply to Level 4 surgical gowns or togas.

Gowns

Minimal-to-Low Barrier Protection

- ANSI/AAMI PB70 Level 1 protection or equivalent
- ANSI/AAMI PB70 Level 2 protection or equivalent

Moderate-to-High Barrier Protection

- ANSI/AAMI PB70 Level 3 protection or equivalent
- ANSI/AAMI PB70 Level 4 protection or equivalent

Enforcement Policy

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.

Devices

- Non-Surgical Gowns and Minimal-to-Low Barrier Protection Surgical Apparel
- Moderate-to-High Barrier Protection Surgical Gowns

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Gloves

BiFeng Qian, Ph.D.
Scientific Reviewer

Gloves

Patient Examination Glove

A disposable device intended for a medical purpose that is worn on the examiner’s hand or finger to prevent contamination between patient and examiner.

Surgeon’s Glove

A device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.

Enforcement Policy Guidance

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

- Follow CDC's recommendations on the use of PPE during the COVID-19 outbreak
- Gloves not intended for medical purposes are not medical devices
- FDA-regulated gloves that are covered by the guidance are listed in the resources section of this presentation
- In effect for the duration of the national emergency

Gloves Not Intended for a Medical Purpose

- When evaluating whether these products are intended for a medical purpose, among other considerations, the FDA will consider whether the product:
  - Is labeled or otherwise intended for use by a health care professional;
  - Is labeled or otherwise for use in a health care facility or environment; and
  - Includes any drugs, biologics, or anti-microbial or anti-viral agent.

Enforcement Policy

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.

Devices

- Patient Examination Gloves
- Surgeon’s Gloves

Resources

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

  Comments may be submitted at any time for Agency consideration.

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

  Comments may be submitted at any time for Agency consideration.

- 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

Resources

- EUA Clarification Letter on Respirators
- Non-NIOSH Approved Respirator EUA FAQ
- Fact Sheet for Healthcare Providers
- 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

Gown Regulations and Product Codes

Classification Regulation	Device Type	Product Code	Class
21 CFR 878.4040	Conductive Shoe and Shoe Cover	BWP	I (exempt)
21 CFR 878.4040	Operating-Room Shoes	FXW	I (exempt)
21 CFR 878.4040	Surgical Apparel Accessory	LYU	I (exempt)
21 CFR 878.4040	Non-surgical isolation gowns	OEA	I (exempt)
21 CFR 878.4040	Surgical suits	FXO	I (exempt)
21 CFR 878.4040	Operating-room shoe covers	FXP	I (exempt)
21 CFR 878.4040	Surgical helmets	FXZ	I (exempt)
21 CFR 878.4040	Surgical dress	FYE	I (exempt)
21 CFR 878.4040	Surgical caps	FYF	I (exempt)
21 CFR 878.4040	Surgical gown/toga	FYA	II
21 CFR 878.4040	Patient gown	FYB	II
21 CFR 878.4040	Surgical isolation gown	FYC	II
21 CFR 878.4040	Surgical hood	FXY	II

Glove Regulation and Product Codes

Classification Regulation	Device Type	Product Code	Class
21 CFR 880.6250	Patient examination glove	FMC	I (reserved)
21 CFR 880.6250	Latex Patient Examination Glove	LYY	I (reserved)
21 CFR 880.6250	Polymer Patient Examination Glove	LZA	I (reserved)
21 CFR 880.6250	Finger Cot	LZB	I (exempt)
21 CFR 880.6250	Vinyl Patient Examination Glove	LYZ	I (reserved)
21 CFR 880.6250	Powder-Free Guayle Rubber Examination Glove	OIG	I (reserved)
21 CFR 880.6250	Powder-Free Polychloroprene Patient Examination Glove	OPC	I (reserved)
21 CFR 880.6250	Radiation Attenuating Medical Glove	OPH	I (reserved)
21 CFR 880.6250	Specialty Patient Examination Glove	LZC	I (reserved)
21 CFR 878.4460	Surgeon's Gloves	KGO	I (reserved)
21 CFR 878.4460	Powder-Free Non-Natural Rubber Latex Surgeon's Gloves	OPA	I (reserved)

Questions?

Division of Industry and Consumer Education: DICE@fda.hhs.gov

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http://www.fda.gov/training/cdrhlearn

Under Heading: Special Technical Topics; Subheading: Device Specific Topics

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