

**SUMMARY OF FDA GUIDANCE FOR MASKS AND FACE
SHIELDS DURING THE COVID-19 OUTBREAK
(Updated through April 6, 2020)**

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I. BACKGROUND

- ❖ The Department of Health and Human Services (HHS) has determined that the COVID-19 outbreak in the United States is a **public health emergency** and the President has **declared a national emergency**.
- ❖ The U.S. Food and Drug Administration (FDA) recognizes the need for additional supplies of personal protective equipment (PPE), including **face masks, surgical masks, respirators (collectively, “masks”) and face shields** to effectively respond to the COVID-19 outbreak.
- ❖ In recent weeks, the FDA has issued several Emergency Use Authorization (EUA) letters and published various guidance documents (including temporary enforcement policies) to **clarify the regulatory landscape** for masks and face shields during the public health emergency, to **provide regulatory flexibility**, and to **help expand the availability** of masks and face shields for use by the general public and health care providers.
- ❖ Those letters and guidance documents (through April 6, 2020) are **listed below**:
 - March 2, 2020 Letter re: NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency, which was amended and reissued on March 28, 2020;
 - March 11, 2020 Letter re: NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency, available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>;
 - March 28, 2020 Letter re: NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency, available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>;
 - March 24, 2020 Letter re: Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which was amended and reissued on March 28, 2020;
 - March 28, 2020 Letter re: Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which is available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>;
 - March 29, 2020 Letter re: Battelle Decontamination System, available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>;
 - April 3, 2020 Letter re: Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which is available at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>;

- March 25, 2020 Guidance Document re: Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency, FDA-2020-D-1138, which was amended and superseded;
 - April 2, 2020 Guidance Document re: Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency, which is available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>;
 - April 6, 2020 Webinar Presentation re: Emergency Policy for Personal Protective Equipment (PPE) During COVID-19, available at: <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-enforcement-policy-personal-protective-equipment-ppe-during-covid-19-immediately-effect>.
- ❖ In general, the FDA has enacted **temporary policies to reduce the regulatory burdens to introduce new PPE, including masks**, to the medical community and general public during the COVID-19 outbreak. Interested companies should **closely follow** FDA requirements for new products. These policies **only apply during the public health emergency**. Companies that want to continue to make and supply products after the public health emergency will likely be required to meet **additional FDA requirements** for medical products.¹
 - ❖ The FDA recommends that **health care providers follow Center for Disease Control (CDC) guidance** on the use of PPE, including gowns and surgical apparel, during the public health emergency.² Additionally, **health care employers must comply with standards of the Occupational Safety and Health Administration (OSHA)** (29 CFR 1910 subpart I), requiring PPE to protect workers.
 - ❖ This document provides a **general overview and summary** of the FDA letters and guidance documents. It is not fact or case specific, and it **does not recommend any particular course of action**. The FDA documents cited herein, and the FDA website, along with any updates, **should be reviewed in consultation** with qualified professionals and/or counsel. Interested parties should also **contact the FDA directly** with questions, and for additional details and guidance.

¹ A list of the classification regulation and associated product codes for masks and face shields covered by current FDA guidance is provided in the April 2, 2020 Guidance Document re: Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency, which is available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>.

² Additional information about CDC recommendations on the use of PPE is available at: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>.

II. OVERVIEW OF MASK TYPES

- ❖ FDA letters and guidance documents generally describe **five categories of masks** that are in **short supply** and/or that were **not originally approved for medical purposes but may be distributed and used for medical purposes** during the public health emergency, including:
 - face masks;
 - surgical masks;
 - N95 respirators;
 - surgical N95 respirators; and
 - other air-purifying respirators approved by the National Institute for Occupational Safety and Health (NIOSH) in accordance with 42 CFR Part 84.
- ❖ Each type is **briefly discussed below**.
- ❖ **Face Masks:**
 - A face mask is a **loose-fitting, disposable** device that covers the user's nose and mouth **to create a physical barrier** between the user and potential contaminants in the immediate environment. It helps to block particles **expelled by the wearer**. It **may or may not include a face shield**.



- The edges are **not designed** to form a seal around the nose and mouth.
- Because a face mask is not designed to fit tight to the face, **leaks may occur around the edges of the mask** when a user inhales, and it **may not effectively filter small particles** from the air.
- Pursuant to FDA letters and guidance documents, unlike other categories of masks intended for medical purposes (e.g., surgical masks and N95 respirators), a face mask is **not required to meet** standards for fluid resistance, particle and bacterial filtration efficiency, flammability, and biocompatibility before distribution, provided that other conditions (discussed below) are met.

- A face mask offers the lowest level protection from particles and fluid in the immediate environment.

➤ **Surgical Masks**

- A surgical mask **has a similar design to a face mask**, but with **fluid resistance**.



- A surgical mask is a **loose-fitting, disposable** device that covers the user's nose and mouth.
- The edges are **not designed** to form a seal around the nose and mouth.
- Because a surgical mask is not designed to fit tight to the face, **leaks may occur around the edges of the mask** when a user inhales, and it **may not effectively filter small particles** from the air.
- Pursuant to FDA letters and guidance documents, surgical masks **must meet** certain standards for **fluid resistance, flammability, and biocompatibility before distribution**.
- Because of that, while (similar to a face mask) it **may not effectively filter small particles** from the air, a surgical mask provides **additional protection to the wearer** against large droplets, sprays, or splashes of bodily or other hazardous fluids. It also **protects the patient** from the wearer's respiratory emissions.

➤ **N95 Respirators:**

- An **N95 respirator** helps to reduced **airborne particles inhaled by the wearer**, e.g., dust, mist, fumes, fibers, and bioaerosols, including bacteria and viruses.
- It is designed to fit **tight to the face** and to **form a seal around** the user's nose and mouth.



- It is tested and certified by NIOSH based on physical and performance characteristics, including filtration efficiency in accordance with 42 CFR Part 84.
- The “N95” designation means that, when subjected to careful testing, the respirator **blocks at least 95% of very small (0.3 micron) test particles**.
- N95 respirators may be intended for **medical purposes** or marketed to the general public for **general, non-medical purposes**, such as use in construction and other industrial applications.
- **In a healthcare setting**, N95 respirators **protect the user from exposure to biological aerosols**, including viruses and bacteria.

➤ **Surgical N95 Respirators:**

- A **surgical N95 respirator** is both:
 - certified by NIOSH as an **N95 respirator**; and
 - cleared by the FDA as a **surgical mask**.³
- It helps to reduce particles **inhaled by the wearer** (like a respirator), and reduce particles **expelled by the wearer** and **resists fluids** (like a surgical mask).
- A surgical N95 respirator must meet the same FDA standards for **fluid resistance, flammability, and biocompatibility** as a surgical mask, before commercial distribution.⁴
- NIOSH and the FDA share responsibility to approve surgical N95 respirators.⁵

³ Additional information about the differences between surgical masks, N95 respirators, and surgical N95 respirators is available at: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respource3healthcare.html.

⁴ The FDA standards for fluid resistance, flammability, and biocompatibility for surgical masks and surgical N95 respirators are described in Guidance for Industry and FDA Staff on Surgical Masks, FDA-2003-D-0305, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions>.

⁵ The FDA and NIOSH have executed a Memorandum of Understanding, available at: <https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006>. Generally, a device is evaluated and certified by NIOSH for filter efficiency

➤ Other NIOSH-Approved Air-Purifying Respirators⁶


- There are **additional air-purifying respirators** approved by NIOSH, which recently, the FDA has approved for use in health care settings during the public health emergency, including:
 - elastometric half-facepiece respirators;

Elastometric Half Facepiece Respirator

- Reusable facepiece and replaceable cartridges or filters
- Can be used to protect against gases, vapors, or particles, if equipped with the appropriate cartridge or filter
- Covers the nose and mouth
- Fit testing required



- elastometric full-facepiece respirators; and



Elastometric Full Facepiece Respirator

- Reusable facepiece and replaceable canisters, cartridges, or filters
- Can be used to protect against gases, vapors, or particles, if equipped with the appropriate cartridge, canister, or filter
- Provides eye protection
- More effective face seal than FFRs or elastometric half-facepiece respirators
- Fit testing required

- power air-purifying respirators.

Powered Air-Purifying Respirator (PAPR)

- Reusable components and replaceable filters or cartridges
- Can be used to protect against gases, vapors, or particles, if equipped with the appropriate cartridge, canister, or filter
- Battery-powered with blower that pulls air through attached filters or cartridges
- Provides eye protection
- Low breathing resistance
- Loose-fitting PAPR does NOT require fit testing and can be used with facial hair
- Tight-fitting PAPR requires fit testing

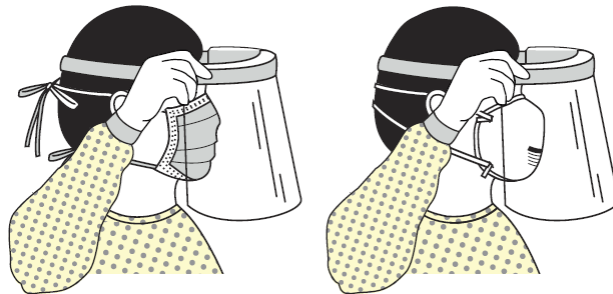


and breathing resistance. The FDA accepts those results and reviews the device for fluid resistance, flammability, and biocompatibility.

⁶ Additional information about NIOSH-approved air purifying respirators is available at: <http://osha10hrtraining.com/blog/worker-safety-articles/n95-day-n95-filtering-facepiece-respirators/>.

III. OVERVIEW OF FACE SHIELDS

- ❖ A face shield is used to **protect the entire face** (including the wearer’s mouth, nose and eyes) from bodily fluids, liquid splashes, or potentially infectious materials.
- ❖ A face shield may be used or combined **with a mask** or, in some cases, used as a **substitute to a mask** (or goggles).⁷



- ❖ It is typically constructed of **plastic**, covering the **forehead**, extending **below the chin**, and wrapping around the **sides of the face**.

⁷ Instructions for the sequence of putting on and safely removing PPE (including masks and face shields) are available at: <https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf>.

IV. MASKS AND FACE SHIELDS THAT ARE INTENDED FOR GENERAL PURPOSES

- ❖ When masks (including face masks, surgical masks, and respirators) and face shields are marketed to the general public for **general, non-medical purposes**, FDA authorization **is not required** and the requirements of the Food, Drug and Cosmetic (FD&C) Act **do not apply**.
- ❖ Masks and face shields are **medical devices** and **subject to FDA oversight** when they are “**intended for a medical purpose**,” meaning they are “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease and, therefore, meet[] the definition of ‘device’ set forth in section 201(h) of the FD&C.”
- ❖ When **evaluating if products are intended for a medical purpose**, FDA considers:
 - if the product is **labeled for use by health care providers** and/or use **in a health care setting**; and
 - if the product **includes drugs, biologics, or anti-microbial or anti-viral agents**.

V. **FDA EFFORTS TO INCREASE FACE MASKS INTENDED FOR MEDICAL PURPOSES (WITHOUT LIQUID BARRIER PROTECTION)**

- ❖ Face mask **distribution and use** has the **least regulatory hurdles** during the public emergency.
- ❖ The FDA **does not intend to object** to the **use and distribution (including importation)** of face masks for medical purposes if they:
 - **do not claim to provide liquid barrier protection**; and
 - **do not create an “undue risk”** to medical personnel or the general public.
- ❖ A face mask **does not create an undue risk** where:
 - the labeling **accurately describes the product as a face mask**, as opposed to a surgical mask or respirator;
 - the product includes **a list of the body contacting materials, which do not include any drugs or biologics**;
 - the **labeling makes recommendations to sufficiently reduce the risk** of use, such as, **recommendations against use of the product**, including:
 - in **surgical settings** or where **significant exposure to liquid, bodily, or other hazardous fluids**, may be expected;
 - in clinical settings **where the risk level through inhalation exposure is high**; or
 - in the presence of a **high intensity heat source or flammable gas**.
 - the product is not recommended or intended for any use that would create an undue risk to the user, for example, the **labeling does not include**:
 - uses for liquid barrier protection;
 - uses for antimicrobial or antiviral protection or reduction;
 - uses for infection prevention or reduction; or
 - **particulate filtration claims**.
- ❖ Provided that a face mask does not create an undue risk, the FDA will **not object if other FDA regulations for medical devices are not satisfied**, including:
 - site registration and product listing under 21 CFR 807;
 - prior submission of a premarket notification under Section 510(k) of the FD&C Act and 21 CFR 807.81;

- good manufacturing practices under 21 CFR 820 (design, manufacture, packaging, labeling, storage, and distribution);
 - reporting, correction, and product removal requirements under 21 CFR 806; and
 - device identification requirements under 21 CFR Part 830 and 21 CFR 801.20.
- ❖ Parties interested in **manufacturing face masks must obtain** a device-specific **Emergency Use Authorization (EUA)** from the FDA.
 - ❖ The FDA has specifically **invited interest** from:
 - **manufacturers of masks that are not currently legally marketed in the US;** and
 - **manufacturers who have not previously been engaged in medical device manufacturing,** such as textile manufacturers.⁸
 - ❖ The FDA has indicated it is providing **maximum regulatory flexibility** where possible and will **expeditiously review** any requests.
 - ❖ The FDA recommends that **existing mask manufacturers whose products are not currently marketed in the US provide the following information** for review:
 - general **contact information,** including the manufacturer’s name and places of business, email address, and the contact information for any US agent;
 - general **product information,** including the proprietary or **brand name** and **model number** of the device, and a **copy of the product labeling;**
 - if the device has **marketing authorization in another regulatory jurisdiction,** including certification number if available;
 - if the device is **manufactured in compliance** with 21 CFR Part 820 or ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes or an equivalent quality system, including documentation of such;

⁸ FDA guidance does not specifically address existing US manufacturers of masks and/or medical devices that want to make changes or modifications to face masks or surgical masks already made and distributed in the US or want to begin manufacturing new products. In the context of ventilators, the FDA has required that existing manufacturers still must submit a request and meet certain safety, performance, and labeling criteria for modified products under FDA guidance and the FDA’s March 24, 2020 emergency use authorization letter concerning ventilators, available at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>. It is reasonable to assume that the FDA will take a similar approach with other products, and that existing manufacturers should contact the FDA at CDRH-COVID19_SurgicalMasks@fda.hhs.gov or CDRH-NONDiagnosticEUA-Templates@fda.hhs.gov, with their planned changes or new products, including: general contact information; a description of the proposed device; and, any testing conducted on the device.

- a **description of testing conducted** on the device, including any standards met, such as, liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate.
- ❖ The FDA recommends that manufacturers **who have not previously been engaged** in medical device manufacturing **but have interest manufacturing face masks** contact the FDA, describing their proposed device and approach. The FDA has stated it will **work collaboratively with new manufacturers** through the EUA process. New manufacturers should generally expect to **provide information**, such as:
 - general **contact information**, including the manufacturer's name and place of business, and email address;
 - **a description of the proposed device and intended use;**
 - a description of **testing conducted** on the device and/or any **available safety and effectiveness information** for the product, as appropriate; and
 - a description of the **manufacturing process for the product and quantity of face masks to be made.**⁹
- ❖ As one example, at least one textile manufacturer has announced plans to manufacture face masks to **wear over surgical masks and respirators**, as a secondary source of protection and to help extend the life of surgical masks and respirators.
- ❖ The FDA will consider each EUA request on a **case-by-case basis** and, if granted, likely will include **additional conditions** appropriate to:
 - ensure that users (whether health care providers or general consumers) **understand the risks and benefits** of the emergency use of the device and available alternatives;
 - **monitor and report adverse events** associated with the emergency use of the device (consistent with 21 CFR Part 803); and
 - ensure manufacturers **keep appropriate records.**
- ❖ Interested manufacturers **should email the FDA**¹⁰ at: CDRH-COVID19SurgicalMasks@fda.hhs.gov or CDRH-NONDiagnosticEUA-Templates@fda.hhs.gov.

⁹ Additional information about the EUA process is provided in Guidance for Industry and Other Stakeholders, Emergency Use Authorization of Medical Products and Related Authorities, FDA-2016-D-1025, is available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>.

¹⁰ In some cases, the FDA has provided multiple (and different) email addresses, which are listed herein.

- ❖ **Additional information** about face masks is provided in:
 - the April 2020 Guidance Document re: Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency, FDA-2020-D-1138, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>;
 - the April 6, 2020 Webinar Presentation re: Emergency Policy for Personal Protective Equipment (PPE) During COVID-19, available at: <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-enforcement-policy-personal-protective-equipment-ppe-during-covid-19-immediately-effect>.

VI. FDA EFFORTS TO INCREASE SURGICAL MASKS INTENDED FOR MEDICAL PURPOSES (WITH LIQUID BARRIER PROTECTION)

- ❖ A surgical mask is a **Class II device** intended to be used in **surgical settings** or where **significant exposure to liquid, bodily, or other hazardous fluids** may be expected.
- ❖ The FDA has **reduced** the regulatory burden to **use and distribute** surgical masks during the public emergency; **but still**, surgical masks **must meet fluid resistance, flammability, and biocompatibility** requirements.
- ❖ The FDA **does not intend to object** to the **use and distribution** of surgical masks for medical purposes if they **do not create an “undue risk”** to the user.
- ❖ A surgical mask **does not create an undue risk** where:
 - the product **meets fluid resistance testing** (liquid barrier performance) consistent with standard ASTM F1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);
 - the product **meets flammability requirements** for Class I or II textiles under 16 CFR 1610, **unless labeled with a recommendation against** use in the presence of a high intensity heat source or flammable gas;
 - the labeling **accurately describes the product as a surgical mask**;
 - the product includes **a list of the body contacting materials, which does not include any drugs or biologics**;
 - the product is not recommended or intended for any use that would create an undue risk to the user, for example, the **labeling does not include**:
 - uses for antimicrobial or antiviral protection or reduction;
 - uses for infection prevention or reduction; or
 - **particulate filtration claims.**
- ❖ While **some performance testing is still required** (and will be reviewed by the FDA) for surgical masks before distribution, **it may be limited to fluid resistance** if the **labeling makes recommendations against use of the product** in the presence of a **high intensity heat source or flammable gas**.
- ❖ Provided that a surgical mask does not create an undue risk, the FDA will **not object if other FDA regulations for medical devices are not satisfied**, including:
 - site registration and product listing under 21 CFR 807;

- prior submission of a premarket notification under Section 510(k) of the FD&C Act and 21 CFR 807.81;
 - good manufacturing practices under 21 CFR 820 (design, manufacture, packaging, labeling, storage, and distribution);
 - reporting, correction, and product removal requirements under 21 CFR 806; and
 - device identification requirements under 21 CFR Part 830 and 21 CFR 801.20.
- ❖ Parties interested in **manufacturing surgical masks must obtain** a device-specific **Emergency Use Authorization (EUA)** from the FDA.
 - ❖ The FDA has specifically **invited interest** from:
 - **manufacturers of masks that are not currently legally marketed in the US;** and
 - **manufacturers who have not previously been engaged in medical device manufacturing,** such as textile manufacturers.¹¹
 - ❖ The FDA has indicated it is providing **maximum regulatory flexibility** where possible and will **expeditiously review** any requests.
 - ❖ The FDA recommends that **existing mask manufacturers whose products are not currently marketed in the US provide the following information** for review:
 - general **contact information**, including the manufacturer’s name and place of business, email address, and the contact information for any US agent;
 - general **product information**, including the proprietary or **brand name** and **model number** of the device, and a copy of the product **labeling**;
 - if the device has **marketing authorization in another regulatory jurisdiction**, including certification number if available;
 - if the device is **manufactured in compliance** with 21 CFR Part 820 or ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes or an equivalent quality system, including documentation of such;

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- a **description of testing conducted** on the device, including any standards met, such as, liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate.
- ❖ The FDA recommends that manufacturers **who have not previously been engaged** in medical device manufacturing **but have interest manufacturing surgical masks** contact the FDA, describing their proposed device and approach. The FDA has stated it will **work collaboratively with new manufacturers** through the EUA process. New manufacturers should generally expect to **provide information**, such as:
 - general **contact information**, including the manufacturer’s name and place of business, and email address;
 - **a description of the proposed device and intended use;**
 - a description of **testing conducted** on the device and/or any **available safety and effectiveness information** for the product, if applicable; and
 - a description of the **manufacturing process for the product and quantity of surgical masks to be made.**¹²
- ❖ For example, the FDA recently explained (<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-further-steps-help-mitigate-supply-interruptions-food-and>) that it is “working with textile manufacturers, including clothing designers, about how [to] repurpose their manufacturing product lines to put them to use to make masks [that] can be used for surgical or other isolation procedures, as the benefits of using them outweigh the risks under current circumstances.”
- ❖ The FDA will consider each EUA request on a **case-by-case basis** and, if granted, likely will include **additional conditions** appropriate to:
 - ensure that users (whether health care providers or general consumers) **understand the risks and benefits** of the emergency use of the device and available alternatives;
 - **monitor and report adverse events** associated with the emergency use of the device (consistent with 21 CFR Part 803); and
 - ensure manufacturers **keep appropriate records.**
- ❖ Interested manufacturers **should email the FDA**¹³ at: CDRH-COVID19SurgicalMasks@fda.hhs.gov or CDRH-NONDiagnosticEUA-Templates@fda.hhs.gov.

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❖ **Additional information** about surgical masks is provided in:

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- the April 6, 2020 Webinar Presentation re: Emergency Policy for Personal Protective Equipment (PPE) During COVID-19, available at: <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-enforcement-policy-personal-protective-equipment-ppe-during-covid-19-immediately-effect>.

VII. FDA EFFORTS TO INCREASE FACE SHIELDS INTENDED FOR MEDICAL PURPOSES

- ❖ The FDA seeks to expand the availability of **face shields** “that **might offer some benefit**” to health care providers and the general public during the COVID-19 outbreak.
- ❖ Face shield **distribution and use** have **lower regulatory hurdles** during the public emergency.
- ❖ The FDA **does not intend to object** to the **distribution and use (including importation)** of face shields intended for medical purposes if they **do not create an “undue risk”** to the user.
- ❖ A face shield **does not create an undue risk** where:
 - the labeling **accurately describes the product as a face shield**;
 - the product includes **a list of the body contacting materials, which do not include any drugs or biologics**;
 - the product **does not contain any materials that will cause flammability**, or the product **meets flammability requirements** for Class I or II textiles under 16 CFR 1610, **unless labeled with a recommendation against** use in the presence of a high intensity heat source or flammable gas;
 - the product is not recommended or intended for any use that would create an undue risk to the user, for example, the **labeling does not include**:
 - uses for antimicrobial or antiviral protection or reduction;
 - uses for infection prevention or reduction; or
 - radiation protection.
- ❖ Provided that a face shield does not create an undue risk, the FDA will **not object if other FDA regulations for medical devices are not satisfied**, including:
 - site registration and product listing under 21 CFR 807;
 - good manufacturing practices under 21 CFR 820 (design, manufacture, packaging, labeling, storage, and distribution);
 - reporting, correction, and product removal requirements under 21 CFR 806; and
 - device identification requirements under 21 CFR Part 830 and 21 CFR 801.20.¹⁴

¹⁴ A face shield is a Class I device and therefore exempt from premarket notification requirements under Section 510(k) of FD&C Act. A face shield combined with a face mask is allowed by current FDA guidance; but face shields combined with other devices, e.g., a gown, hood, or toga, are not and require separate inquiries to the FDA.

- ❖ Current FDA guidance **does not specifically address manufacturing** face shields. However, the FDA **appears to be treating face shields similar to face masks**. As a starting point, interested manufacturers **should consider following the recommendations for face masks** (discussed in Section V, above) to contact the FDA and discuss increasing manufacturing capacity or manufacturing new face shields.

VIII. FDA EFFORTS TO INCREASE RESPIRATORS INTENDED FOR MEDICAL PURPOSES

- ❖ The FDA **has not amended requirements to manufacture** N95 respirators (and surgical 95 respirators) intended for medical purposes, **nor has NIOSH**.
- ❖ An N95 respirator intended for medical purposes **must still meet** particle filtration, flammability, and biocompatibility requirements. A surgical N95 respirator **must also meet** the fluid resistance requirements for surgical masks.
- ❖ **It may be difficult to expect many new manufacturers** for N95 respirators (and surgical N95 respirators) to emerge given the product specifications and complexity, and supply shortages due to worldwide demand.
- ❖ The **premarket criteria** to clear N95 respirators intended for medical purposes includes testing for:
 - filtration efficiency;
 - differential pressure;
 - biocompatibility;
 - flammability; and
 - fluid resistance (for surgical N95 respirators).¹⁵
- ❖ Manufacturers **must comply with other FDA requirements** for medical devices, including:
 - site registration and product listing under 21 CFR 807;
 - premarket notification¹⁶ under Section 510(k) of the FD&C and 21 CFR 807.81;
 - good manufacturing practices under 21 CFR 820;

¹⁵ These test standards are further described in the following:

(1) Guidance for Industry and FDA Staff, Surgical Masks, FDA-2003-D-0305, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions>; and

(2) November 2017 Memorandum of Understanding between the FDA and NIOSH, available at: <https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006>.

¹⁶ N95 respirators are exempt for premarket notification requirements (*see* 21 CFR 878.4040(b)(1)) under the following conditions:

- (i) The user contacting components of the device must be demonstrated to be biocompatible.
- (ii) Analysis and nonclinical testing must:
 - (A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and
 - (B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.
- (iii) NIOSH approved under its regulation.

- reporting, correction, and product removal requirements under 21 CFR 806; and
 - device identification requirements under 21 CFR Part 830.
- ❖ Still, the FDA has indicated that it will **expedite review of manufacturing site changes and/or premarket submissions** to increase supplies of PPE (including N95 respirators), and that interested manufacturers should contact the FDA at: deviceshortages@fda.hhs.gov, CDRH-COVID19-SurgicalMasks@fda.hhs.gov or CDRH-NONDiagnosticEUA-Templates@fda.hhs.gov.¹⁷
- ❖ Furthermore, besides increasing manufacturing capacity, the FDA is taking **additional steps to increase distribution and use (including importation)** of respirators during the public health emergency, including:
- the emergency use of **all air-purifying respirators for general use approved by NIOSH;**
 - the emergency use of **NIOSH-approved respirators (by strategic stockpilers) that have passed the manufacturer's recommend shelf-life;**
 - the emergency use of **non-NIOSH-approved respirators;** and
 - the emergency use of **decontaminated respirators.**
- ❖ Those additional steps are **summarized below.**

¹⁷ In July 2007, the FDA issued Special Controls Guidance for Industry and FDA Staff, Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies, available at: <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/filtering-facepiece-respirator-use-general-public-public-health-medical-emergencies-class-ii-special>. That document described certain information required for abbreviated submission under Section 510(k) of the FD&C. That document has not been cited by the FDA in recent guidelines or letter, but still may provide some insight into how the FDA will process requests to manufacture N95 respirators during the public health emergency.

VIII.A. THE EMERGENCY USE OF ALL AIR-PURIFYING RESPIRATORS APPROVED BY NIOSH

- ❖ On March 2, 2020 and March 28, 2020, the FDA **authorized the emergency use of all air-purifying respirators** (including N95 respirators, elastomeric half-facepiece and full-facepiece respirators, and power air-purifying respirators) **approved by NIOSH for general use in accordance with 42 CFR Part 84, and listed on:**
 - the NIOSH Certified Equipment List for non-power air purifying respirators with particulate protection, which is available at:
https://www2a.cdc.gov/drds/cel/cel_results.asp?startrecord=1&Search=cel_form&maxrecords=50&schedule=84A&appdatefrom=&appdateto=&facepiecetype=Filtering+Facepiece&facepiecetype=Full+Facepiece&facepiecetype=Half+Mask&facepiecetype=Quarter+Mask&powered=&scbatype=&scbause=&privatelabel=; and
 - the NIOSH Certified Equipment List for power air-purifying respirators with particulate protection, which is available at:
https://www2a.cdc.gov/drds/cel/cel_results.asp?startrecord=1&Search=cel_form&maxrecords=50&schedule=21C&contaminant=41&appdatefrom=&appdateto=&powered=&scbatype=&scbause=&privatelabel=
- ❖ Respirators approved for emergency use **are eligible for the liability protections** of the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.
- ❖ The manufacturers of listed respirator models **will be notified by the FDA**; they **do not need to contact the FDA** to ask that models are included or authorized for emergency use.
- ❖ A manufacturer **may withdraw** some or all of the authorized models for emergency use by notifying the FDA at: CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov, with a copy to the CDC at: RecordsRoom@cdc.gov.
- ❖ The FDA has **waived good manufacturing practices** under 21 CFR 820; however, the manufacturers of authorized respirators **must:**
 - have a **process in place for reporting adverse events** of which they become aware, and send such reports to the FDA;
 - **maintain all records** associated with the authorized respirators until otherwise notified by the FDA; and
 - **make all such records available** to the FDA for inspection upon request.
- ❖ **Importers** of authorized respirators **must:**
 - **notify authorized manufacturers** of the terms and conditions of FDA emergency use;
 - **ensure that end user facilities** (e.g., hospitals) **receive notice** of the terms and conditions of FDA emergency use; and

- **maintain all records** relating to authorized respirators for the duration (i.e., until the end of) the COVID-19 public health emergency.
- ❖ All **descriptive printed matter** for authorized respirators **must** be:
 - consistent with labeling approved by NIOSH;
 - consistent with CDC recommendations for use during the COVID-19 outbreak; and
 - consistent with FDA emergency authorization.
- ❖ **No descriptive printed matter** for approved respirators **may represent or suggest the product is safe or effective** for preventing COVID-19.
- ❖ **When importing** respirators subject to FDA emergency use, **entry information should be submitted to the FDA**; however, reduced FDA information is required for review.
- ❖ At the time of entry, the **importer should transmit**:
 - **Intended Use Code 940.000**: Compassionate Use/Emergency Use Device; and
 - **an appropriate FDA product code**, such as - Masks/Respirators: 80NZJ.¹⁸
- ❖ Under this Intended Use Code, the Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are **optional** in the Automated Commercial Environment (ACE) system.¹⁹
- ❖ The **FDA can be contacted** at: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov or 301-796-0356 with questions, and to resolve entry issues for shipments.

¹⁸ U.S. Customs and Border Protection has issued two relevant bulletins (#42124872 and #42168200), available at: https://content.govdelivery.com/bulletins/gd/USDHSCBP-282c648?wgt_ref=USDHSCBP_WIDGET_2; and <https://content.govdelivery.com/accounts/USDHSCBP/bulletins/2836f88>.

¹⁹ Additional information regarding entry submission requirements in the ACE system, is available at: <https://www.fda.gov/industry/import-systems/automated-commercial-environmentinternational-trade-data-system-acetids>; and <https://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16>.

VIII.B. THE EMERGENCY USE OF NIOSH-APPROVED RESPIRATORS THAT HAVE PASSED THE RECOMMENDED SHELF-LIFE

- ❖ On March 2, 2020 and March 28, 2020, the FDA **authorized the emergency use of all NIOSH-approved respirators** (including N95 respirators, elastomeric half-facepiece and full-facepiece respirators) **that have passed the manufacturer’s recommended shelf-life**, but are **not damaged**, and have been **held in strategic stockpiles** in accordance with the manufacturer’s recommended storage conditions.
- ❖ Strategic stockpilers **do not need to notify the FDA** before distributing authorized respirators if acting consistent with FDA emergency authorization, including that:
 - to the extent feasible, stockpilers **maintain reports of adverse events** received from health care providers and facilities receiving the respirators;
 - **the adverse events that stockpilers become aware of are reported** to the FDA via MedWatch Forms for FDA Safety Reporting;
 - stockpilers **alert and instruct recipients** to check the integrity of respirators prior to use; and
 - stockpilers **maintain all records** associated with authorized respirators until otherwise notified by the FDA and **make all such records available** to the FDA for inspection upon request.
- ❖ Expired respirators that are **damaged or in disrepair are not authorized** for distribution or use.

VIII.C. THE EMERGENCY USE OF NON-NIOSH-APPROVED RESPIRATORS (EXCLUDING CHINA)

- ❖ On March 24, 2020 and March 28, 2020, the FDA **authorized the emergency use** (and marketing, distribution, and importation) of **certain respirators without NIOSH approval**, but that are considered **N95-equivalent**.
- ❖ To be eligible, respirators **must**:
 - **meet the applicable standards** in place in Australia, Brazil, Europe, Japan, Korea, or Mexico; or
 - **be authorized** for marketing in Europe, Australia, Canada, or Japan.
- ❖ A **list of currently approved respirators** is available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>;
- ❖ To **request the authorization of respirators**, manufacturers and/or importers must email the FDA at: CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov, with their intention to import non-NIOSH approved respirators, make a request to be authorized, and provide the following information:
 - the manufacturer, model number(s), and marketing authorization/certificate from another regulatory authority or conformity assessment body acting on their behalf, including the authorization number (if any);
 - a certificate of conformity (if available);
 - the applicable performance standards that the product meets;
 - any applicable guidance documents;
 - an estimate of the number of respirators planning to be imported; and
 - a copy of the product labeling.
- ❖ Upon receipt, the FDA will **confirm eligibility** and **notify the manufacturer** if the respirators are authorized.
- ❖ The FDA has **waived good manufacturing practices** under 21 CFR 820; however, **manufacturers** of authorized respirators **must**:
 - **publish the intended use and other product instructions** (including, fit testing) for all authorized models **on the manufacturer's website in English**, notify the FDA by email at: CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov, of the website address (URL) meeting these conditions, and notify the FDA of any changes to the website;

- **include a letter, in English**, that can be distributed to end users and facilities with at least, **the name of the manufacturer and model, the intended use, and the manufacturer’s website**, and ensure that **all end user facilities receive the letter**;
 - **notify the importer** (if any) of the conditions of FDA emergency authorization;
 - have a **process in place for reporting adverse events** of which the manufacturer becomes aware, and send such reports to the FDA;
 - **maintain all records** associated with the authorized respirators until otherwise notified by the FDA; and
 - **make all such records available** to the FDA for inspection upon request.
- ❖ **Importers** of authorized respirators **must**:
- notify the manufacturer of the conditions of FDA emergency authorization;
 - ensure that **all end user facilities receive the aforementioned letter**; and
 - **maintain all records** associated with the authorized respirators until the end of the public health emergency.
- ❖ All **descriptive printed matter** for authorized respirators **must** be:
- consistent with CDC recommendations²⁰ for use during the COVID-19 outbreak; and
 - consistent with FDA emergency authorization.
- ❖ **No descriptive printed matter** for approved respirators **may represent or suggest the product is safe or effective** for preventing COVID-19.
- ❖ Respirator manufacturers whose country standards or approval mechanism **are not already part** of FDA emergency authorization can submit a **separate request** for emergency use at: CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov, with the text “Non-NIOSH-Approved Respirator” in the subject line and include:
- general information, such as the manufacturers’ contact information, name and place of business, email address, and contact information for a U.S. agent (if any);
 - general information about the device, such as the proprietary or brand name, model number, and marketing authorization;
 - a copy of the product labeling;

²⁰ Information about CDC recommendations is available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>; and <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>.

- whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number, if available);
- whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes or an equivalent quality system and the manufacturer or importer has documentation of such; and
- a description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate.

VIII.D. THE EMERGENCY USE OF NON-NIOSH-APPROVED RESPIRATORS MADE IN CHINA

- ❖ On April 3, 2020, the FDA **authorized the emergency use of certain respirators without NIOSH approval made in China** and that are **validated, reviewed, and authorized by the FDA**.
- ❖ Respirators must meet **one of three criteria to be eligible** for FDA authorization, which are:
 - the respirator is manufactured by an entity holding one or more NIOSH approvals for other respirator models and is produced in accordance with the applicable authorization standards in other countries that can be verified by the FDA;
 - the respirator has regulatory authorization under a jurisdiction other than China that can be authenticated and verified by the FDA; or
 - the respirator demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by the FDA.
- ❖ A **list of currently approved respirators** is attached as Appendix A to the FDA’s April 3, 2020 letter and available at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>.
- ❖ To **request the authorization of respirators**, manufacturers and/or importers must email the FDA at: CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov, with the subject line “FFRS Made in China,” **demonstrating that the proposed respirator meets one of the three criteria** outlined above.²¹
- ❖ Upon receipt, the FDA will **confirm eligibility** and **notify the manufacturer** if the respirators are authorized.
- ❖ The FDA has **waived good manufacturing practices** under 21 CFR 820; however, **manufacturers** of authorized respirators **must**:
 - **publish the intended use and other product instructions** (including, fit testing) for all authorized models **on the manufacturer’s website in English**, notify the FDA by email at: CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov, with the subject line “URL for FFR Made in China,” of the website address (URL) meeting these conditions, and notify the FDA of any changes to the website;
 - **include a letter, in English**, that can be distributed to end users and facilities with at least, **the name of the manufacturer and model, the intended use, and the manufacturer’s website**, and ensure that **all end user facilities receive the letter**;

²¹ Additional details about the content of the email is found at page 4 of the FDA’s April 3, 2020 letter.

- **notify the importer** (if any) of the conditions of FDA emergency authorization;
 - have a **process in place for reporting adverse events** of which the manufacturer becomes aware, and send such reports to the FDA;
 - **maintain all records** associated with the authorized respirators until otherwise notified by the FDA; and
 - **make all such records available** to the FDA for inspection upon request.
- ❖ **Importers** of authorized respirators **must**:
- notify the manufacturer of the conditions of FDA emergency authorization;
 - ensure that **all end user facilities receive the aforementioned letter**; and
 - **maintain all records** associated with the authorized respirators until the end of the public health emergency.
- ❖ All **descriptive printed matter** for authorized respirators **must** be:
- consistent with CDC recommendations²² for use during the COVID-19 outbreak; and
 - consistent with FDA emergency authorization.
- ❖ **No descriptive printed matter** for approved respirators **may represent or suggest the product is safe or effective** for preventing COVID-19.

²² Information about CDC recommendations is available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>; and <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>.

VIII.E. THE EMERGENCY USE OF DECONTAMINATED RESPIRATORS

- ❖ On March 28, 2020, the FDA **authorized the emergency use** of respirators that have been **decontaminated pursuant to the terms and conditions of an authorized decontamination system**, and on March 29, 2020, the FDA granted emergency **authorization of the first such system**, known as the “Battelle Decontamination System.”
- ❖ The Battelle Decontamination System is designed for **N95 respirators and N95-equivalent respirators**.
- ❖ It can **only be operated by Battelle Memorial Institute** and cannot be distributed to third parties.
- ❖ The FDA is interested **working with additional manufacturers** to reprocess N95 respirators.
- ❖ The FDA has indicated that it will work with interested manufacturer to **expedite market authorization** to increase respirator supplies, and that interested manufacturers should contact the FDA at: CDRH-COVID19-SurgicalMasks@fda.hhs.gov.
- ❖ The **relevant criteria for evaluation and information requested** by the FDA is described in the March 2020 Guidance Document re: Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency, FDA-2020-D-1138, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>, and **generally includes**:
 - a description of the process for disinfection/reprocessing control;
 - evidence to demonstrate validation of bioburden reduction/disinfection;
 - a description of chain of custody and safeguards to prevent inadvertent exposure;
 - evidence to demonstrate material compatibility;
 - evidence to demonstrate filtration performance;
 - fit test data; and
 - a copy of the reprocessed device product labeling, which the FDA recommends should:
 - clearly state the mask is reprocessed;
 - identify how many times the mask may be reprocessed;
 - advise users to discard masks that are visibly damaged or that fit poorly and not reprocess; and

- identify materials (including filter and strap/elastic band) that are incompatible with your proposed reprocessing cycle.

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