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# **Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)**

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## **Guidance for Industry and Food and Drug Administration Staff**

September 2021

**This document supersedes “Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)” issued May 2020.**

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health (CDRH)  
Office of Product Evaluation and Quality (OPEQ)**

# Preface

## Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

## Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, and the FDA webpage titled "Search for FDA Guidance Documents," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an additional copy of the guidance. Please include the document number 20018 and complete title of the guidance in the request.

## Questions

For questions about this document, contact 1-888-INFO-FDA or [CDRH-COVID19-SurgicalMasks@fda.hhs.gov](mailto:CDRH-COVID19-SurgicalMasks@fda.hhs.gov)

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## **Guidance for Industry and Food and Drug Administration Staff**

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

### **I. Introduction**

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability of face masks, barrier face coverings, and face shields for the general public, including healthcare personnel (HCP)<sup>1</sup>, and

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<sup>1</sup> For purposes of this guidance, healthcare personnel (HCP) refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

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surgical masks and particulate filtering facepiece respirators (FFRs) (including N95 respirators) for HCP for the duration of the COVID-19 public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).<sup>2</sup>

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

## **II. Background**

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2,” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.<sup>3</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>4</sup>

FDA believes the policy set forth in this guidance may help address these urgent public health

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<sup>2</sup> Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

<sup>3</sup> Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued on Jan. 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

<sup>4</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at: <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID-19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic (February 24, 2021), available at <https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic>.

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concerns by clarifying the regulatory landscape of face masks, barrier face coverings, face shields, surgical masks, and respirators, and helping to expand the availability of these devices for use by the general public and HCP in healthcare settings, as appropriate.

This document supersedes the guidance, “Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised),” issued May 2020. The May 2020 version revised the guidance, “Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)” issued April 2020, to include recommendations about alternatives when FDA-cleared or National Institute for Occupational Safety and Health (NIOSH)-approved N95 respirators are not available and to remove FDA’s prior recommendations regarding emergency use authorizations (EUAs) for decontamination of face masks and FFRs. The April 2020 version revised the original guidance, “Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency,” issued March 25, 2020, to include face shields and to provide FDA’s recommendations regarding alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available. This version includes barrier face coverings intended for a medical purpose but not intended to provide liquid barrier protection within the scope of this guidance, and provides FDA’s recommendations regarding submicron particulate filtration efficiency, airflow resistance, and leakage assessments for these devices, as well as labeling recommendations, as described in ASTM F3502-21: *Standard Specification for Barrier Face Coverings*. Additionally, this revision removes reference to use of alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available based on current Centers for Disease Control and Prevention (CDC) and FDA recommendations that healthcare facilities should not be using crisis capacity strategies at the time of issuance of this guidance.<sup>5</sup> This revision further adds a policy that, during the public health emergency, FDA generally does not intend to object to stockpiled, non-NIOSH-approved disposable FFRs being further distributed and used as face masks for source control (as opposed to use as FFRs for respiratory protection) by the general public and HCP where such use does not create an undue risk in light of the public health emergency.

### **III. Scope**

There are many products marketed in the United States as “face masks” that offer a range of protection against potential health hazards. Face masks,<sup>6</sup> barrier face coverings, face shields, and respirators are regulated by FDA when they meet the definition of a device under section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Generally, face masks, barrier face coverings, and face shields fall within this definition when they are intended for a medical purpose, including for use by HCP.<sup>7</sup> Face masks that are not intended for a medical purpose are not medical devices, as described in further detail below. Air-purifying respirators (generally referred to as

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<sup>5</sup> <https://www.fda.gov/news-events/press-announcements/fda-brief-fda-revokes-emergency-use-authorizations-certain-respirators-and-decontamination-systems>

<sup>6</sup> FDA also considers face mask and surgical mask accessories that are intended to help hold the mask to the face (e.g., surgical mask strap holders, tension release bands) to fall within the scope of this guidance. Respirator accessories are not included in the scope of this guidance.

<sup>7</sup> As used in this guidance “intended for a medical purpose” means that the device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease and, therefore, meets the definition of “device” set forth in section 201(h)(1) of the FD&C Act.

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“respirators” for the purposes of this guidance) are also regulated by NIOSH under 42 CFR Part 84 and their use in the workplace is enforced by the Occupational Safety and Health Administration (OSHA) under the OSHA Respiratory Protection Standard at 42 CFR 1910.134. FDA-regulated face masks, barrier face coverings, face shields, surgical masks, and respirators are listed in Table 1:

**Table 1**

<b>Classification Regulation</b>	<b>Device Type</b>	<b>Product Code<sup>8</sup></b>
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Accessory, Surgical Apparel (Face Shield) <sup>9</sup>	LYU
	Surgical mask with antimicrobial/antiviral agent	OUK
	Respirator, Surgical	MSH
	N95 Respirator with Antimicrobial/Antiviral Agent	ONT
21 CFR 880.6260	N95 Respirator with Antimicrobial/Antiviral Agent for Use by the General Public in Public Health Medical Emergencies	ORW
21 CFR 880.6260	Respirator, N95, for Use by the General Public in Public Health Medical Emergencies	NZJ
Not classified	Face Mask Within the Scope of the Face Mask Enforcement Policy or Face Mask Umbrella EUA	QKR <sup>10</sup>
Not classified	Barrier Face Covering Within the Scope of the Face Mask Enforcement Policy	QOZ <sup>11</sup>

This policy does **NOT** apply to other types of masks including but not limited to those in Table 2.

**Table 2**

<b>Classification Regulation</b>	<b>Device Type</b>	<b>Product Code</b>
21 CFR 868.5450	Humidifier, Respiratory Mask	OBN
	Humidifier, Respiratory Gas	BTT
21 CFR 868.5550	Mask, Anesthetic, Gas	BSJ

<sup>8</sup> For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

<sup>9</sup> The scope of this guidance is limited to face shields and their accessories that are intended to help hold the face shield to the face under product code LYU, “Accessory, Surgical Apparel.” Face shields and their accessories that are intended to help hold the face shield to the face are class I devices and are exempt from premarket notification requirements under section 510(k) of the FD&C Act. See 21 CFR 878.4040. Face shields combined with devices other than a face mask (e.g., a gown, hood or toga) are not within the scope of this guidance. See “Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health>.

<sup>10</sup> This product code was created for face masks described in Section IV of this guidance. Face masks that are authorized by the Face Mask Umbrella EUA may also use this product code. This product code did not exist prior to the COVID-19 pandemic.

<sup>11</sup> This product code has been created to describe barrier face coverings, as described in Section IV of this guidance. This product code did not exist prior to the COVID-19 pandemic.

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21 CFR 868.5580	Mask, Oxygen	BYG
21 CFR 868.5600	Mask, Oxygen, Low Concentration, Venturi	BYG
21 CFR 868.5570	Mask, Oxygen, Non-Rebreathing	KGB
21 CFR 868.5905	Resuscitator, Manual, Non Self-Inflating	NHK
	Mask, Ventilator, Non-Continuous, Reprocessed	NMC
21 CFR 868.5560	Strap, Head, Gas Mask	BTK

FDA recognizes that when personal protective equipment (PPE), such as FDA-cleared or FDA-authorized surgical masks, is unavailable, individuals, including HCP, might improvise. FDA-cleared or FDA-authorized surgical masks should be used whenever possible. However, FDA does not intend to object to individuals' distribution and use of improvised PPE when FDA-cleared or FDA-authorized surgical masks are not available.

## **IV. Definitions**

For the purposes of this guidance, the following definitions are used.

**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. Face masks are for use by the general public and HCP as source control in accordance with CDC recommendations.<sup>12,13</sup>

**Barrier Face Covering** – As described in ASTM F3502-21, a barrier face covering is a product worn on the face, specifically covering at least the wearer's nose and mouth, with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter.

**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 1 or Class 2 flammability tests.<sup>14</sup>

**Filtering Facepiece Respirator<sup>15</sup>** – A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.

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<sup>12</sup> Source control refers to the use of a face mask or barrier face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19. See also <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>.

<sup>13</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>.

<sup>14</sup> CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.

<sup>15</sup> Unless otherwise indicated in this document, filtering facepiece respirators are approved by NIOSH.



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**N95 Respirator** – A disposable filtering facepiece respirator that covers the user’s airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.170. Such an N95 respirator used in a healthcare setting is approved by NIOSH under 42 CFR Part 84 and regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II 510(k)-cleared device.

**Surgical N95 Respirator** – A disposable FFR used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per NIOSH under 42 CFR 84.170. A surgical N95 respirator is approved by NIOSH and regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.<sup>16</sup>

## **V. Policy**

### **A. Overview**

FDA is taking steps to expand the availability of face masks, barrier face coverings, face shields, surgical masks, and respirators, and believes the policy set forth in this guidance may help address the urgent public health concerns caused by shortages of such products by taking a risk-based approach and clarifying the policies that FDA intends to apply to these products, including their associated indications and claims.

### **B. Face Masks, Face Shields, and Respirators Not Intended for a Medical Purpose**

Face masks, face shields, and respirators are devices when they meet the definition of a device set forth in section 201(h)(1) of the FD&C Act. Under section 201(h)(1) of the FD&C Act, these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

Other face masks, face shields, and respirators are marketed to workplaces and the general public for general, non-medical purposes, such as use in construction and other industrial applications. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, FDA device marketing authorization is **not** required, and all the other requirements of the FD&C Act do **not** apply to manufacturers, importers, and distributors of these products.

Face masks, face shields, and respirators are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Face

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<sup>16</sup> A Memorandum of Understanding between NIOSH and FDA (available at <https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006>) further explains the regulatory paradigm for these devices. Additional information for manufacturers of these devices can be found at <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2018-1010-R1.html>.

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masks, face shields, and respirators are not devices when they are intended for a non-medical purpose, such as for use in construction. When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider whether:

- 1) they are labeled or otherwise intended for use by HCP;
- 2) they are labeled or otherwise for use in a healthcare facility or environment; and
- 3) they include any drugs, biologics, or anti-microbial/anti-viral agents.

### **C. Face Masks and Barrier Face Coverings Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection**

In general, FDA recommends that HCP follow current CDC guidance regarding PPE that should be used during the COVID-19 outbreak.<sup>17</sup> Healthcare employers must also comply with OSHA standards that require PPE to protect workers and that apply to infectious disease hazards.<sup>18</sup>

Throughout the pandemic, FDA has consistently recommended that face masks are to be used for source control, and are not personal protective equipment.<sup>19</sup> Additionally, FDA now recommends that barrier face coverings can also be used for source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter. By definition, these devices should meet the submicron particulate filtration efficiency, airflow resistance, and leakage assessment recommendations as described in ASTM F3502-21. However, neither face masks nor barrier face coverings are a substitute for NIOSH-approved respirators (including N95 respirators), which provide respiratory protection to the wearer, or for surgical masks, which provide fluid barrier protection and particulate filtration to the wearer.

In the April 2, 2020 publication of this guidance, FDA provided flexibility regarding distribution and use of face masks without compliance with certain regulatory requirements, including submission of a 510(k) under certain circumstances. FDA's policy was based on the evolving public health emergency and the increased need for devices for source control. In addition to this policy and in response to the shortage of face masks, on April 18, 2020, FDA issued an Emergency Use Authorization ([EUA](#)) [for certain face masks](#)<sup>20</sup> that FDA determined met the criteria for issuance under Section 564 of the FD&C Act. This EUA has succeeded in increasing the availability of face masks for HCP and the general public for use as source control when FDA-cleared or -approved face masks are not available.

To help foster the availability of equipment that might offer some benefit to HCP and the general public during the COVID-19 outbreak, FDA is continuing its April 2, 2020, policy regarding face masks, recognizing there is some overlap with the EUA. Furthermore, FDA is also including barrier face coverings within the scope of this policy given that they may be used as source control that also

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<sup>17</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>.

<sup>18</sup> See 29 CFR Part 1910, subpart I.

<sup>19</sup> See FDA's EUA for face masks (non-surgical) available at <https://www.fda.gov/media/137121/download> and FAQs on the Emergency Use Authorization for Face Masks (Non-Surgical) available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorization-face-masks-non-surgical>.

<sup>20</sup> <https://www.fda.gov/media/137121/download>.

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provides some measured degree of particulate filtration. Thus, for the duration of the public health emergency, FDA does not intend to object to the distribution and use of face masks and barrier face coverings, with or without a face shield (not including respirators), that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face mask or barrier face covering does not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81; Registration and Listing requirements in 21 CFR 807; Quality System Regulation requirements in 21 CFR Part 820; Reports of Corrections and Removals in 21 CFR Part 806; and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. In addition, FDA generally does not intend to object, for the duration of the public health emergency, to the further distribution and use of existing stockpiles of non-NIOSH-approved disposable FFRs for use as face masks for source control (as opposed to use as FFRs for respiratory protection) by the general public and HCP without compliance with the aforementioned regulatory requirements, where the non-NIOSH-approved FFR does not create an undue risk in light of the public health emergency. This policy aims to provide flexibility in situations where healthcare facilities, states, and other stakeholders continue to have a supply of such FFRs following CDC's and FDA's recommendations to return to conventional capacity strategies and following FDA's revocation of the non-NIOSH-approved FFR EUAs.<sup>21</sup>

FDA currently believes such face masks would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a face mask (as opposed to a barrier face covering, surgical mask, or respirator)<sup>22</sup> and includes a list of the body-contacting materials;
- For non-NIOSH-approved FFRs to be used as face masks, the non-NIOSH-approved FFR is segregated from NIOSH-approved FFRs and clearly identified as a face mask for use as source control only;
- The product does not include any drugs, biologics, or nanoparticles;
- The product includes labeling that recommends against use in certain environments, such as recommendations against use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high-intensity heat source or flammable gas;<sup>23</sup> and
- The product is not intended for any use that would create an undue risk in light of the public health emergency; for example, the labeling does not include uses for antimicrobial or

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<sup>21</sup> See Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities, available at <https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators>.

<sup>22</sup> As mentioned, during the public health emergency, FDA generally does not intend to object to stockpiled, non-NIOSH-approved respirators being further distributed and used as face masks for source control (as opposed to being used as FFRs for respiratory protection) where the non-NIOSH-approved FFR is segregated from NIOSH-approved FFRs and clearly identified as a face mask to be used for source control only.

<sup>23</sup> See footnote 22.

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antiviral protection, infection prevention or reduction, or related uses; and the labeling does not include uses for particulate filtration.<sup>24</sup>

FDA currently believes such barrier face coverings would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a barrier face covering (as opposed to a face mask, surgical mask, or respirator) and includes a list of the body-contacting materials;
- The product does not include any drugs, biologics, or nanoparticles;
- The product includes labeling that recommends against use in certain environments, such as recommendations against use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; 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 in light of the public health emergency; for example, the labeling does not include uses for antimicrobial or antiviral protection, infection prevention or reduction, or related uses; and
- The product is labeled as a barrier face covering and is evaluated in accordance with 42 CFR Part 84 and consistent with ASTM F3502-21: *Standard Specification for Barrier Face Coverings*.<sup>25</sup> This includes assessments of submicron particulate filtration efficiency and airflow resistance. The product is also labeled consistent with, and meets, the design, leakage assessment, material, and flammability criteria as described in the standard.

### **D. Face Shields Intended for a Medical Purpose**

In general, FDA recommends that HCP follow current CDC guidance regarding PPE that should be used during the COVID-19 outbreak.<sup>26</sup> Healthcare employers must also comply with OSHA standards that require PPE to protect workers and that apply to infectious disease hazards.<sup>27</sup> To help foster the availability of equipment that might offer some benefit to HCP and the general public 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 shields that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face shield does not create an undue risk in light of the public health emergency: Registration and Listing requirements in 21 CFR Part 807; Quality System Regulation requirements in 21 CFR Part 820; Reports of Corrections and Removals in 21 CFR Part

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<sup>24</sup> See footnote 22.

<sup>25</sup> Please refer to the FDA's Recognized Consensus Standards database for additional considerations regarding use of this standard: [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard\\_identification\\_no=42029](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=42029).

<sup>26</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>.

<sup>27</sup> See 29 CFR Part 1910, subpart I and OSHA's COVID-19 Healthcare Emergency Temporary Standard (ETS), available at <https://www.osha.gov/coronavirus/ets>.

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806; and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.<sup>28</sup> FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a face shield and includes a list of the body-contacting materials (which does not include any drugs, biologics, or nanoparticles);
- The face shield does not contain any materials that will cause flammability, or the product meets Class 1 or Class 2 flammability requirements per 16 CFR Part 1610 (unless labeled with a recommendation against use in the presence of high-intensity heat source or flammable gas);
- The product is not intended for any use that would create an undue risk in light of the public health emergency; for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses, or for radiation protection.

### **E. Surgical Masks Intended to Provide Liquid Barrier Protection**

Surgical masks are class II devices that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials. They are tested for flammability and biocompatibility, and are considered PPE. For the duration of the declared public health emergency, FDA does not intend to object to the distribution and use of surgical masks without compliance with the following regulatory requirements where the surgical mask does not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81; Registration and Listing requirements in 21 CFR Part 807; Quality System Regulation requirements in 21 CFR Part 820; Reports of Corrections and Removals in 21 CFR Part 806; and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.<sup>29</sup> FDA currently believes such devices would not create such an undue risk where:

- The product meets fluid resistance testing (liquid barrier performance) consistent with standard ASTM F1862<sup>30</sup> Standard Test Method for Resistance of Medical Face Masks to

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<sup>28</sup> In addition to this policy and in response to the shortage of face shields, on April 9, 2020, and revised on April 13, 2020, FDA issued an EUA for certain face shields that FDA determined met the criteria for issuance under Section 564 of the FD&C Act. This EUA has succeeded in increasing the availability of face shields for HCP as PPE in healthcare settings to cover the front and sides of the face and provide barrier protection when FDA-cleared or -approved face shields are not available. See <https://www.fda.gov/media/136842/download>.

<sup>29</sup> In addition to this policy and in response to the shortage of surgical masks, on August 5, 2020, FDA issued an EUA for certain surgical masks that FDA determined met the criteria for issuance under Section 564 of the FD&C Act. This EUA has succeeded in increasing the availability of surgical masks for HCP in healthcare settings as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles when FDA-cleared or -approved surgical masks are not available. See <https://www.fda.gov/media/140894/download>.

<sup>30</sup> For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at

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Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);

- The product meets Class 1 or Class 2 flammability requirements per 16 CFR Part 1610 (unless labeled with a recommendation against use in the presence of high-intensity heat source or flammable gas);
- The product includes labeling that accurately describes the product as a surgical mask and includes a list of the body-contacting materials (which does not include any drugs, biologics, or nanoparticles); and
- The product is not intended for any use that would create an undue risk in light of the public health emergency; for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses, or uses for infection prevention or reduction or related uses, and does not include particulate filtration claims.

## **VI. EUAs for Face Masks Intended for a Medical Purpose, Surgical Masks, Face Shields, and Respirators**

Wherever possible, healthcare facilities should continue to use FDA-cleared surgical masks and NIOSH-approved air-purifying respirators and/or NIOSH-approved and FDA-cleared respirators. In response to the COVID-19 pandemic, FDA issued an EUA that authorizes [NIOSH-approved air-purifying respirators](#)<sup>31</sup> for use in healthcare settings by HCP. In addition, as mentioned in Section V above, EUAs have also been issued for [face masks](#) for use by the general public and HCP as source control,<sup>32</sup> and [surgical masks](#),<sup>33</sup> and [face shields](#) for use by HCP in healthcare settings.<sup>34</sup> These EUAs have helped increase availability of these devices to HCP and the general public, as applicable, during the public health emergency.

For any face mask or respirator (including N95 respirators) issued an EUA, FDA will include appropriate conditions of authorization in accordance with section 564 of the FD&C Act. Although this is a case-by-case determination, based on current information and experience, we will likely include the following conditions:

- Appropriate conditions designed to ensure that HCP administering the device are informed—
  - that FDA has authorized the emergency use of the device;

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<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

<sup>31</sup> <https://www.fda.gov/media/135763/download>. FDA previously authorized for emergency use certain non-NIOSH-approved FFRs. However, effective July 6, 2021, FDA revoked those EUAs. See <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#ppe>.

<sup>32</sup> <https://www.fda.gov/media/137121/download>.

<sup>33</sup> <https://www.fda.gov/media/140894/download>.

<sup>34</sup> <https://www.fda.gov/media/136842/download>.

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- of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
- of the alternatives to the device that are available, and of their benefits and risks.
- Appropriate conditions designed to ensure that individuals to whom the device is administered are informed—
  - that FDA has authorized the emergency use of the device;
  - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
  - of the option to accept or refuse administration of the device, of the consequence, if any, of refusing administration of the device, and of the alternatives to the device that are available and of their benefits and risks.
- Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the device. FDA intends to include conditions that are consistent with those promulgated under 21 CFR Part 803.
- For manufacturers of the device, appropriate conditions concerning recordkeeping and reporting, including records access by FDA, with respect to emergency use of the device.