Contains Nonbinding Recommendations

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

Guidance for Industry and Food and Drug Administration Staff

May 2020

This document supersedes "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)" issued April 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 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

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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 general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for healthcare personnel (HCP)[1] 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

[1] As used in the three EUAs for filtering facepiece respirators in effect at the time 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).

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.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and 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, the HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3]

FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by HCP in healthcare settings.

This document supersedes the guidance, "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)," issued April 2020. 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 additional updates regarding alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available and removes FDA's prior recommendations regarding emergency use

[2] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.
[3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

authorizations (EUAs) for decontamination of face masks and filtering facepiece respirators.[4]

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[5] and respirators are regulated by FDA when they meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Generally, face masks fall within this definition when they are intended for a medical purpose, including for use by HCP.[6] Face masks that are not intended for a medical purpose are not medical devices, as described in further detail below. FDA-regulated face masks and respirators are listed in Table 1:

Table 1

Classification Regulation	**Device Type**	**Product Code[7]**
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Accessory, Surgical Apparel (Face Shield)[8]	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

[4] Concurrently with issuance of this revised guidance, the FDA is issuing the guidance, "Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."

[5] 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.

[6] 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) of the FD&C Act.

[7] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[8] The scope of this guidance is limited to face shields and their accessories that are intended to help to hold the face shield to the face under product code LYU, "Accessory, Surgical Apparel." Face shields and their accessories that are intended to help to hold the face shield to the face are class I devices and are exempt from premarket notification requirements under 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.

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

Table 2

Classification Regulation	Device Type	Product Code
21 CFR 868.5450	Humidifier, Respiratory Mask	OBN
	Humidifier, Respiratory Gas	BTT
21 CFR 868.5550	Mask, Anesthetic, Gas	BSJ
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 surgical masks or respirators, are unavailable, individuals, including HCP, might improvise. FDA does not intend to object to individuals' distribution and use of improvised PPE when FDA-cleared or authorized surgical masks or respirators 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 only as source control in accordance with CDC recommendations.[9, 10]

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

Surgical Mask – A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests.[11]

Filtering Facepiece Respirator – 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.

[9] Source control refers to the use of a facemask or cloth 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.
[10] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.
[11] CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.

N95 Respirator – A disposable half-mask filtering facepiece respirator (FFR) that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is 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.

NIOSH Approved N95 Respirator – An N95 respirator, approved by NIOSH that meets filtration efficiency level per 42 CFR 84.181.

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 42 CFR 84.181. A surgical N95 respirator is 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.

V. Policy

A. Overview

FDA is taking steps to expand the availability of face 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 masks and respirators, including these products' associated indications and claims.

B. Face Masks, Face Shields, and N95 Respirators Not Intended for a Medical Purpose

Face masks, face shields, and N95 respirators are devices when they meet the definition of a device set forth in section 201(h) of the FD&C Act. Under section 201(h) 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 FFRs are marketed to 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 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 a HCP;
2) they are labeled or otherwise for use in a health care facility or environment; and
3) they include any drugs, biologics, or anti-microbial/anti-viral agents.

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

In general, FDA recommends that HCP follow current Centers for Disease Control and Prevention (CDC) guidance regarding personal protective equipment (PPE) that should be used during the COVID-19 outbreak.[12] Health care employers must also comply with standards of the Occupational Safety and Health Administration (OSHA) that require PPE to protect workers and that apply to infectious disease hazards.[13] Face masks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for FFRs or for surgical face masks.[14]

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 EUA for certain face masks[15] that FDA determined met the criteria for issuance under Section 564 of the 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 face masks are not available.

Wherever possible, HCP and the general public should continue to use FDA-cleared face masks as source control or, when those are not available, face masks authorized under the EUA. However, 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. Thus, for the duration of the public health emergency FDA does not intend to object to the distribution and use of face masks, 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 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 820, Reports of Corrections and Removals in 21 CFR Part 806, and Unique

[12] https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html.
[13] *See* 29 CFR 1910 subpart I.
[14] 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.
[15] https://www.fda.gov/media/137121/download.

Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. 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 mask (as opposed to a surgical mask or FFR) and includes a list of the body contacting materials (which does not include any drugs or biologics);

- The product includes labeling that makes recommendations that would reduce sufficiently the risk of use, for example, 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; 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.

D. Face Shields Intended for a Medical Purpose

In general, FDA recommends that HCP follow current Centers for Disease Control and Prevention (CDC) guidance regarding PPE that should be used during the COVID-19 outbreak.[16] Health care employers must also comply with standards of the Occupational Safety and Health Administration (OSHA) that require PPE to protect workers and that apply to infectious disease hazards.[17] 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 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. 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, or biologics);

- The face shield does not contain any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);

[16] https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html.
[17] *See* 29 CFR 1910 subpart I.

- 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 and are tested for flammability and biocompatibility. 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 807, Quality System Regulation requirements in 21 CFR 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. 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[18] 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 Class I or Class II flammability requirement per 16 CFR 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 or biologics); 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.

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

F. Alternatives When FDA-Cleared or NIOSH-Approved N95 Respirators are Not Available

CDC published on its website Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies,[19] which, as part of a set of crisis management recommendations, identifies alternatives to FDA-cleared or NIOSH-approved N95 respirators approved under standards used in other countries, some of which were evaluated under methods that are similar to NIOSH-approved N95 respirators.

In the April 2, 2020 publication of this guidance, FDA provided flexibility regarding distribution and use of respirators identified in the CDC recommendations 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 increasing need for respiratory protection devices for HCP, which was rapidly outpacing the supply of FDA-cleared or NIOSH-approved respirators. The guidance also recommended that importers take appropriate steps to verify the authenticity of products they import.

In addition to this policy and in response to the shortage of respirators, FDA issued emergency use authorizations (EUAs) for certain respirators that FDA determined met the criteria for issuance under Section 564 of the Act.[20] These EUAs have succeeded in increasing the availability of respirators for HCP when FDA-cleared or NIOSH-approved respirators are not available.

Since the April 2, 2020 publication of this guidance, FDA has become aware of concerns regarding the performance of certain respirators based on testing conducted by the CDC.[21] This indicates that greater FDA oversight of respirators that are not FDA-cleared or authorized under an EUA is important to protect the public health. As a result of these changed circumstances, FDA is discontinuing its previous policy from April 2, 2020 under which FDA did not intend to object to the distribution and use of certain respirators that were not FDA-cleared or authorized under an EUA and did not meet other regulatory requirements.

FDA currently believes that FDA-cleared or NIOSH-approved N95 respirators should be used when they are available, but when they are not, FDA recommends using FDA-authorized respirators before any other alternatives. This is consistent with the CDC's approach for optimizing the supply of N95 respirators. FDA does not recommend using a product as a respirator unless it has been FDA-cleared, NIOSH-approved, or authorized by FDA for emergency use as a respirator. Such a product could instead be used as a face mask by the general public and HCP as source control when certain criteria are met under the EUA for face masks.[22] In that case, the product should be labeled accordingly and not used as a respirator.[23]

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[19] https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html.

[20] See FDA's webpage regarding emergency use authorizations, available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe.

[21] https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html.

[22] https://www.fda.gov/media/137121/download.

[23] Source control refers to the use of a facemask or cloth 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.

In addition, FDA notes that HCP should ensure that respirators adequately fit. Hospitals and end users should be aware that it may be difficult to achieve an adequate fit when wearing respirators with ear loops instead of head straps. When proper fit is not achieved for a respirator, it should not be used as a respiratory protective device.

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

Wherever possible, health care facilities should continue to use FDA-cleared surgical masks and NIOSH-approved and/or FDA-cleared N95 respirators, or better. In response to the COVID-19 pandemic, FDA has also issued EUAs that authorize certain FFRs, including NIOSH-approved FFRs,[24] imported non-NIOSH-approved disposable FFRs from certain jurisdictions excluding China,[25] and non-NIOSH-approved disposable FFRs manufactured in China,[26] for use in healthcare settings by HCP. These EUAs are intended to help increase availability of these devices to front-line personnel during the public health emergency. FDA has also issued an EUA for face masks[27] for use by the general public and HCP as source control.

For devices that do not fall within the scope of these EUAs, FDA is interested in interacting with manufacturers on additional device-specific EUAs. This may include manufacturers of masks and respirators that are not currently legally marketed in the US as well as manufacturers who have not previously manufactured masks or respirators with capabilities to increase supply of these devices.

FDA would find it helpful if such manufacturers (whether foreign or domestic) send FDA the following information to CDRH-COVID19-SurgicalMasks@fda.hhs.gov; FDA believes this information will be valuable in assessing whether the device would be able to meet the EUA requirements. FDA believes that companies may already have available information to help support an EUA request such as the information outlined below. FDA will expeditiously review this information, and other required information,[28] to determine whether the device can be authorized under an EUA.

1) For current face mask and respirator manufacturers whose product(s) are not currently marketed in the US, FDA recommends providing the following information:
    a. General information such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any) in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region).
    b. A copy of the product labeling.
    c. Whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number, if available).

[24] https://www.fda.gov/media/135763/download.
[25] https://www.fda.gov/media/136403/download.
[26] https://www.fda.gov/media/136664/download.
[27] https://www.fda.gov/media/137121/download.
[28] See Section 564 of the FD&C Act.

d. 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.
e. Description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate. For surgical N95 respirators, FDA recommends including fluid resistance testing (liquid barrier performance).

2) For face mask manufacturers who have not previously been engaged in medical device manufacturing but with capabilities to increase supply of these devices:

   FDA welcomes the opportunity to work with manufacturers not previously engaged in medical device manufacturing with the interest and capability to manufacture face masks and respirators. This may include US manufacturers in other manufacturing sectors. These manufacturers should send an email to the address above and describe their proposed approach. FDA intends to work collaboratively with these manufacturers through its EUA process.

For any face mask or FFR (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;
  - 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.