This guidance is intended to remain in effect until November 7, 2023, unless superseded by a revised final guidance before that date. For further information, refer to 88 FR 15417, March 13, 2023, available at https://www.federalregister.gov/d/2023-05094.

Contains Nonbinding Recommendations

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

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Guidance for Industry and Food and Drug Administration Staff

Document issued on March 13, 2023

This document supersedes "Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)" issued September 2021.

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-SurgicalMasks@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2020-D-1138.

Additional Copies

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00007007 and complete title of the guidance in the request.

Contains Nonbinding Recommendations

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

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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.

This policy is intended to remain in effect for 180 days following expiration of the COVID-19 public health emergency declaration under section 319 of the Public Health Service Act (42 U.S.C. 247d(a)(2)), unless a different intended duration is set forth in a finalized version of the FDA guidance, "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease. For further information, please refer to the Federal Register notice titled "Guidance Documents Related to Coronavirus Disease 2019 (COVID-19)."[1]

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

[1] *See* 88 FR 15417, March 13, 2023, available at: https://www.federalregister.gov/d/2023-05094.

guidance was implemented without prior public comment because FDA had determined that prior public participation for this guidance was 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 was 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.[2]

In general, FDA's guidance documents 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 guidances means that something is suggested or recommended, but not required.

II. Background

In 2019, an outbreak of respiratory disease caused by a novel coronavirus began. 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.[3] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[4]

The policy set forth in this guidance was intended to help address these urgent public health concerns by clarifying the regulatory landscape of face shields, surgical masks, and respirators, and helping to expand the availability of these devices for use by the general public and health care personnel (HCP)[5] in healthcare settings, as appropriate.

This document supersedes the guidance, "Enforcement Policy for Face Masks, Barrier Face

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[2] *Available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

[3] 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.

[4] 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.

[5] 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).

Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)," issued September 2021. The September 2021 version revised the guidance "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)," issued May 2020 to further add a policy that, during the public health emergency, FDA generally does not intend to object to stockpiled, non-National Institute for Occupational Safety and Health (NIOSH)-approved disposable FFRs being further distributed and used as face masks for source control[6] (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. 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 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. The September 2021 version included barrier face coverings intended for a medical purpose but not intended to provide liquid barrier protection within the scope of this guidance, and provided 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, the September 2021 revision removed 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.[7] The current guidance splits the previous version of the guidance into two separate guidance documents, each with identical policy to their corresponding parts of the September 2021 version.[8] This bifurcation of the previous versions does not affect the current policy and is intended only to facilitate a different timeline and process for transitioning back to normal operations for specific device types.

III. Scope

Face shields and respirators are regulated by FDA when they meet the definition of a device under section 201(h)(1) of the FD&C Act. Generally, face shields fall within this definition when they are

[6] 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.

[7] https://www.fda.gov/news-events/press-announcements/fda-brief-fda-revokes-emergency-use-authorizations-certain-respirators-and-decontamination-systems

[8] Concurrent with issuance of this guidance, FDA also is issuing "Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-barrier-face-coverings-during-coronavirus-disease-covid-19-public.

intended for a medical purpose, including for use by HCP.[9] Air-purifying respirators (generally referred to as "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 shields, surgical masks,[10] and respirators are listed in Table 1:

Table 1

Classification Regulation	**Device Type**	**Product Code[11]**
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Accessory, Surgical Apparel (Face Shield)[12]	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

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

[9] 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.

[10] FDA also considers 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.

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

[12] 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.

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 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.[13]

Filtering Facepiece Respirator[14] – 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.

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

[13] CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.
[14] Unless otherwise indicated in this document, filtering facepiece respirators are approved by NIOSH.

notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.[15]

V. Policy

A. Overview

In response to the COVID-19 pandemic, FDA has taken steps to expand the availability of face shields, surgical masks, and respirators, and the policy set forth in this guidance was intended to 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 Shields and Respirators Not Intended for a Medical Purpose

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 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 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 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 Shields Intended for a Medical Purpose

In general, FDA recommends that HCP follow current CDC guidance regarding PPE that should be

[15] 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.

used during the COVID-19 outbreak.[16] Healthcare employers must also comply with OSHA standards 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 declaration and for 180 days following its expiration, unless a different intended duration is set forth in a finalized version of the FDA guidance, "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease, 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 806; and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.[18] 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.

D. 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 declaration and for 180 days following its expiration, unless a different intended duration is set forth in a finalized version of the FDA guidance, "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," *available at*

[16] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.
[17] *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.
[18] 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.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease, 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.[19] 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[20] 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 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 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-

[19] 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.

[20] 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.

purifying respirators[21] for use in healthcare settings by HCP. In addition, as mentioned in Section V above, EUAs have also been issued for surgical masks[22] and face shields for use by HCP in healthcare settings.[23] These EUAs have helped increase availability of these devices to HCP and the general public, as applicable, during the public health emergency.

For any surgical mask, face shield, or respirator (including N95 respirators) issued an EUA, FDA has included 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, subsequent EUAs, if authorized, would 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.

[21] 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.
[22] https://www.fda.gov/media/140894/download.
[23] https://www.fda.gov/media/136842/download.