Contains Nonbinding Recommendations

Enforcement Policy for Face Masks and Barrier Face Coverings for Coronavirus Disease (COVID-19) Response

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Guidance for Industry and Food and Drug Administration Staff

Document issued on September 5, 2023

This document supersedes "Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency" issued March 2023.

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

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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 only for the duration of the declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Secretary of Health and Human Services (HHS) on March 24, 2020 that circumstances exist justifying the authorization of emergency use of devices, including alternative products used as devices (85 FR 17335).[1] This policy is intended to remain in effect for the duration of that declaration, unless FDA revises or replaces this guidance.

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

[1] Available at https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration.
[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

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 masks and barrier face coverings and helping to expand the availability of these devices for use by the general public and healthcare personnel (HCP)[5] in healthcare settings, as appropriate.

This document supersedes the guidance, "Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)," issued March 2023. The March 2023 version of the guidance had split the previous version of the guidance, "Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)," into two separate guidance documents. This bifurcation of the earlier version contained identical policies to the corresponding parts of the September 2021 version and did not affect the policy. Rather, it was intended only to facilitate a different timeline and process for transitioning back to normal operations for specific device types. For more information, see the March 13, 2023 Federal Register notice entitled "Guidance Documents Related to Coronavirus Disease 2019 (COVID-19)."[6]

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[3] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued on Jan. 31, 2020, subsequently renewed, and expired on May 11, 2023), *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).

[6] See "Guidance Documents Related to Coronavirus Disease 2019 (COVID-19)" (88 FR 15417), *available at* https://www.federalregister.gov/documents/2023/03/13/2023-05094/guidance-documents-related-to-coronavirusdisease-2019-covid-19.

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 filtering facepiece respirators (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. 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: *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] Consistent with the March 13, 2023 Federal Register notice,[8] the current guidance has been revised to align with the duration of the relevant declaration supporting authorization of emergency use under section 564 of the FD&C Act.

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[9] and barrier face coverings are regulated by FDA when they meet the definition of a device under section 201(h)(1) of the FD&C Act. Generally, face masks and barrier face coverings fall within this definition when they are intended for a medical purpose, including for use by HCP.[10] 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 barrier face coverings subject to this guidance are listed in table 1:

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

[8] See footnote 6.

[9] FDA also considers face mask accessories that are intended to help hold the mask to the face (e.g., strap holders, tension release bands) to fall within the scope of this guidance.

[10] 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.

Table 1

Classification Regulation	Device Type	Product Code[11]
Not classified	Face Mask Within the Scope of the Face Mask and Barrier Face Covering Enforcement Policy or Face Mask Umbrella EUA	QKR[12]
Not classified	Barrier Face Covering Within the Scope of the Face Mask and Barrier Face Covering Enforcement Policy	QOZ[13]

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

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.[14]

Barrier Face Covering – As described in the ASTM F3502 standard, a barrier face covering is a product worn on the face, specifically covering at least the wearer's nose and mouth, with the

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

[12] 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.

[13] 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.

[14] 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 an infectious disease. See also https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.

primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter.

V. Policy

A. Overview

In response to the COVID-19 pandemic, FDA has taken steps to expand the availability of face masks and barrier face coverings. 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 Masks Not Intended for a Medical Purpose

Face masks 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 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 are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission. Face masks 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 use of personal protective equipment (PPE) that should be used during the COVID-19 outbreak.[15] Healthcare employers must also comply with Occupational Safety and Health Administration standards that

[15] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.

require PPE to protect workers and that apply to infectious disease hazards.[16]

FDA recommends that face masks are to be used for source control, and are not personal protective equipment.[17] Additionally, FDA 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 the ASTM F3502 standard. 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, in April 2020, FDA issued an EUA for certain face masks[18] 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, 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 provides some measured degree of particulate filtration. Thus, while this policy is in effect, 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: 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. In addition, FDA generally does not intend to object, while this policy is in effect, 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. 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

[16] See 29 CFR Part 1910, subpart I.
[17] 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.
[18] https://www.fda.gov/media/137121/download.

non-NIOSH-approved FFR EUAs.[19]

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)[20] 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;[21] and
- The product is not intended for any use that would create an undue risk; for example, the labeling does not include uses for antimicrobial or antiviral protection, infection prevention or reduction, or related uses; and the labeling does not include uses for particulate filtration.[22]

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;

[19] 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.
[20] As mentioned, 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.
[21] See footnote 20.
[22] See footnote 20.

- The product is not intended for any use that would create an undue risk; 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 the currently FDA recognized version of ASTM F3502: *Standard Specification for Barrier Face Coverings*.[23] 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.

VI. EUAs for Face Masks Intended for a Medical Purpose

As mentioned in Section V above, EUAs have been issued for face masks for use by the general public and HCP as source control.[24] 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 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.

[23] 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.
[24] https://www.fda.gov/media/137121/download.

- For manufacturers of the device, appropriate conditions concerning recordkeeping and reporting, including records access by FDA, with respect to emergency use of the device.