April 24, 2020

To: Manufacturers of Face Masks;
Health Care Personnel;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders.

On April 18, 2020, in response to concerns relating to insufficient supply and availability of face masks,[1,2] the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) authorizing the use of face masks for use by members of the general public, including health care personnel (HCP)[3] in healthcare settings as personal protective equipment (PPE), to cover their noses and mouths, in accordance with Centers for Disease Control and Prevention (CDC) recommendations, to prevent the spread of the virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States

[1] A face mask is a device, 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. It includes cloth face coverings as a subset. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a "device" under section 201(h) of the Act. Generally, face masks fall within this definition when they are intended for a medical purpose. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks).

[2] Surgical masks are not covered within the scope of this authorization. Surgical masks are masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are regulated under 21 CFR 878.4040 as class II devices requiring premarket notification. Additionally, these masks meet certain fluid barrier protection standards and Class I or Class II flammability tests. More information on the distinction is provided in FDA guidance, titled "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" available at https://www.fda.gov/media/136449/download.

[3] 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 HCP 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).

citizens living abroad, and that involves the virus that causes COVID-19.[4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[5]

On April 24, 2020 in response to questions and concerns that have been received by FDA since issuance of the April 18, 2020 letter of authorization and having concluded that revising the April 18, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the April 18, 2020 letter in its entirety with amendments[6] incorporated. Specifically, FDA is clarifying through this re-issued letter that facemasks, including cloth face coverings, are authorized to be used by HCP only as source control[7,8] in accordance with CDC recommendations under this EUA.[9] As stated in the April 18 letter, face masks are authorized for use by the general public to cover their noses and mouths, in accordance with CDC recommendations.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of face masks for use in accordance with CDC recommendations, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

For the most current CDC recommendations on the use of face masks by the general public during COVID-19, please visit CDC's webpage: Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission For the most recent recommendations on use of face masks by HCPs in a healthcare setting, see: Strategies to Optimize the Supply of PPE and Equipment.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of face masks in accordance with CDC recommendations as source control as described in the Scope of Authorization (Section II) to

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[4] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020)

[5] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

[6] The amendments to the April 18, 2020 letter clarify that the eligible facemasks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for filtering face piece respirators or for surgical face masks. This reissued EUA does not change any aspects of the April 18, 2020 letter with respect to the use of face masks by the general public.

[7] 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.

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

[9] In addition, health care employers should refer to standards of the Occupational Safety and Health Administration (OSHA) that apply to PPE to protect workers and infectious disease hazards. *See* 29 CFR 1910 subpart I.

help prevent spread of the virus during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face masks may be effective as source control to help prevent the spread of SARS-CoV-2 by infected individuals who may or may not have symptoms of COVID-19 during the COVID-19 pandemic, and that the known and potential benefits of face masks, when used in accordance with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of face masks for source control by the general public and for HCPs to help prevent the spread of the virus due to face mask shortages during the COVID-19 pandemic.[10,11]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of face masks, including cloth face coverings, as source control for use by members of the general public, as well as HCP in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of the SARS-CoV-2 during the COVID-19 pandemic. The facemasks are not intended to be used by HCPs as PPE, meaning they are neither substitutable for respiratory protective devices such as filtering face piece respirators, nor for surgical face masks. This use is consistent with face masks regulated as Class I 510(k)-exempt face masks under 21 CFR 878.4040.

Authorized Face Masks

Face masks are authorized under this EUA when they are intended for use as source control, by members of the general public as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic. Authorized face masks must meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);

[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[11] Providing authorization for the introduction into interstate commerce of face masks by manufacturers that do not customarily engage in the manufacture of medical devices helps meet the needs of the healthcare system. In addition, increased availability of face masks helps meet the needs for source control for the general population, reserving FDA-cleared surgical masks and FDA-cleared or -authorized N95 and N95 equivalent Face Filtering Respirators for use by HCP. Providing HCP who are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to help prevent HCP exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
4. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction;
5. The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration; and
6. The product is not labeled for use in high risk aerosol generating procedures.[12]

Manufacturers of face masks that are used as described above and meet the above requirements (i.e., are within this section (the Scope of Authorization, Section II)) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA's posting and public announcement of this EUA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization, serves as face mask manufacturers' notification of authorization.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of face masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that face masks may be effective as described within this section (the Scope of Authorization, Section II) of this letter, pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I of this letter, and concludes that face masks (as described in this section, the Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of face masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), face masks, as source control, are authorized for use by members of the general public, as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.

[12] Examples of aerosol generating procedures in healthcare settings may be found at https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html

III. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under sections 520(f)(1). FDA grants that waiver, including the quality system requirements under 21 CFR Part 820 and labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements in 21 CFR Part 830 and 21 CFR 801.20, except that face masks must include the labeling elements specified in the Conditions of Authorization (Section IV).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers and Distributors of Authorized Products[13]

A. Manufacturers and Distributors will make face masks available with labeling that includes a description of the product as a face mask, including a list of the body contacting materials (which does not include any drugs or biologics).

B. Manufacturers and Distributors of authorized products shall not label the product: 1) as a surgical mask, to provide liquid barrier protection; 2) for use in a clinical setting where the infection risk level through inhalation exposure is high; 3) for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses; 4) as a respiratory protective device; or 5) for high risk aerosol-generating procedures.

C. Manufacturers must make the required labeling available to each end user or end user facility (each hospital) in hard copy or in an alternative format (e.g., electronic labeling on the manufacturer's website). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

D. Manufacturers and Distributors will include instructions for recommended cleaning and/or disinfection materials and processes, if applicable, for their authorized product(s). Manufacturers must provide these instructions, if applicable, to each end user or end user facility (e.g., each hospital) in hard copy or in an alternative format (e.g., electronic instructions). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

[13] The requirements under 21 CFR Part 806 (Reports of Corrections and Removals) and 21 CFR Part 807 (Registration and Listing) do not apply to products authorized under an EUA. As such, compliance with these regulations are not required under this EUA.

E. Manufacturers will have a process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA. See FDA's webpage "Medical Device Reporting (MDR): How to Report Medical Device Problems"[14] for reporting requirements and procedures.[15]

F. Manufacturers and distributors will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

G. Through a process of inventory control, manufacturers and distributors will maintain records of the entities to which they distribute the face masks and the numbers of each such product they distribute.

H. Manufacturers and distributors are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Conditions Related to Advertising and Promotion

I. All printed matter, including advertising and promotional materials, relating to the use of the authorized face mask shall be consistent with the labeling elements listed in Section II of this EUA, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

J. No printed matter, including advertising or promotional materials, relating to the use of the authorized face mask may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.

K. All advertising and promotional descriptive printed matter relating to the use of the product shall clearly and conspicuously state that

- The product has not been FDA cleared or approved
- The product has been authorized by FDA under an EUA for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices,

[14] FDA guidance, titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

[15] Also refer to FDA guidance, titled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic" available at https://www.fda.gov/media/72498/download.

during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration