

April 13, 2020

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

On April 9, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) in response to concerns relating to insufficient supply and availability of face shields¹ for use by health care personnel (HCP) as personal protective equipment (PPE) in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection during the Coronavirus Disease 2019 (COVID-19) pandemic.

On April 13, 2020, in response to questions from stakeholders regarding the authorization process, and having concluded that revising the April 9, 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 9, 2020, letter in its entirety with an amendment incorporated to clarify that this letter of authorization, as posted and publicly announced on FDA's website at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe>, serves as face shield manufacturers' notification of authorization. As stated in the April 9, 2020 letter, manufacturers of authorized face shields do not need to take any action, other than complying with the Conditions of Authorization (Section IV) in this letter of authorization, to be an authorized face shield under this EUA if the face shield is within the Scope of Authorization (Section II).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (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 citizens living abroad, and that involves the virus that causes COVID-19.² Pursuant to Section 564 of the Act, and on the basis of such determination,

¹ 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. Face shields can be intended for medical or nonmedical (e.g., industrial) purposes. Face shields intended for a medical purpose are regulated by FDA under 21 CFR 878.4040 – Surgical apparel. These devices are classified as class I (general controls) and are exempt from the premarket notification requirements in 21 CFR Part 807 ("510(k) clearance"). FDA is issuing this EUA in light of availability concerns to help increase the availability of currently marketed and new face shields for medical purposes during the COVID-19 pandemic. Such face shields may provide "minimal or low barrier protection," meaning Level 1 or Level 2 protection or equivalent under the FDA-recognized standard ANSI/AAMI PB70: *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*.

² U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that

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.³

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 certain face shields for use by HCP as PPE in health care settings 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 shields during COVID-19, please visit CDC's webpage: [Strategies to Optimize the Supply of PPE and Equipment](#).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of face shields for use by HCP as PPE in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection 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 shields may be effective at preventing HCP exposure to fluid biological airborne particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer, and that the known and potential benefits of face shields, when used to prevent HCP exposure to such particulates during face shield shortages during COVID-19 outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of these face shields for preventing HCP exposure to such particulates during face shield shortages to prevent disease spread during the COVID-19 pandemic.^{4,5}

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)

³ 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).

⁴ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

⁵ There are not sufficient quantities of face shields to meet the needs of the U.S. healthcare system. These articles of PPE are an integral part of patient care during the COVID-19 pandemic, particularly during intubation of patients prior to administration of mechanical ventilation. Providing authorization for the introduction into interstate commerce of face shields by manufacturers that do not customarily engage in the manufacture of medical devices helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

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 shields by HCP as PPE in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection during the COVID-19 pandemic.

Authorized Face Shields

Face shields for use by HCP as PPE are authorized under this EUA when they are intended for use by HCP as PPE in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection and meet the following requirements:

- A. The product is labeled accurately to describe the product as a face shield for medical purposes and includes a list of the body contacting materials (which does not include any drugs or biologics);
- B. The product is not integrated with any other article of PPE such as a face mask, but rather is for use as a standalone face shield.
- C. The product includes labeling that describes the product as intended for either a single-user, single use, or for multiple uses by the same user, and includes instructions for recommended cleaning and/or disinfection materials and processes, if applicable.
- D. 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);
- E. 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 state that use of the authorized face shield alone will prevent infection from microbes or viruses, or that it is effective against radiation protection. As indicated in Section I, face shields authorized by this EUA may be effective at preventing HCP exposure to certain particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer during COVID-19. All manufacturers are reminded that they must comply with all Conditions of Authorization, including those relating to advertising and promotion in Section IV of this letter.

Manufacturers of authorized face shields do not need to take any action, other than complying with the Conditions of Authorization (Section IV) in this letter of authorization, to be an authorized face shield under this EUA if the face shield is within the Scope of Authorization (Section II) of this EUA. FDA is clarifying through this re-issued letter of authorization that this letter, as posted and publicly announced on FDA's website at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe>, serves as face shield 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 shields for use by HCPs as PPE, when used and labeled

consistently with the Scope of Authorization of this letter (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 shields may be effective at preventing HCP exposure to certain particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer during COVID-19, when used consistently with the Scope of Authorization of this letter (Section II), 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 above, and concludes that face shields for use by HCP as PPE (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of face shields 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 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 shields authorized to be used by HCP as PPE under the terms and conditions of this EUA.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain FDA Requirements

I am waiving the following requirements for face shields during the duration of this EUA:

- applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the authorized face shields used in accordance with this EUA; and
- labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements (see Subpart B of 21 CFR Part 801), except that face shields 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

- A. Manufacturers and Distributors will make face shields available with the following labeling: (1) the product must be labeled accurately to describe the product as a face shield for medical purposes and include a list of the body contacting materials (which does not include any drugs or biologics), and; (2) the product must include labeling that describes the product as intended for either a single-user, single use, or for multiple uses by the same user. Manufacturers must provide such labeling to each end user facility (e.g., each hospital) that receives the authorized face shield by including a letter, in English, with this information, and may include such labeling with each individual authorized product.
- B. 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 facility (e.g., each hospital) that receives the authorized face shield, and may include such instructions on each individual authorized product.
- C. 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](#)"⁶ for reporting requirements and procedures.
- D. Manufacturers 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.
- E. Through a process of inventory control, manufacturers will maintain records of the entities to which they distribute the face shields and the numbers of each such product they distribute.
- F. Manufacturers 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

- G. All printed matter, including advertising and promotional materials, relating to the use of the authorized face shield 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.

⁶ <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

- H. No printed matter, including advertising or promotional materials, relating to the use of the authorized face shield may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.
- I. 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 by healthcare providers as personal protective equipment.
 - This product is only authorized for the duration of the declaration that circumstances justifying the authorization of emergency use under Section 564(b)(1) of the Act, 21 USC 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 the authorization of the emergency use of medical devices due to shortages during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration