Emergency Use Authorization of Face Shields for use by Health Care Personnel

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 shields 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.

The following is a summary of the April 13, 2020 Re-issue of an Emergency Use Authorization, meant to clarify that the letter itself serves as the EUA, provided the face shield is within the Scope and Conditions of Authorization.

NOTE: UVA is currently developing a labeling insert for face shields to meet the intent of FDA's labeling requirements. Once available, this will be added as an addendum to this document.

Scope of Authorization

FDA Authorized Face Shields

Face shields for use by Health Care Personnel (HCP) as PPE are authorized under FDA's Emergency Use Authorization 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. 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.

Note: Manufacturers of authorized face shields do not need to take any action, other than complying with the **Conditions of Authorization** to be an authorized face shield under this EUA if the face shield is within the **Scope of Authorization** of this EUA.

Conditions of 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" 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.

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.