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FDA Issues EUA for Limited Use Face Masks

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On April 18, 2020, in response to the ongoing COVID-19 pandemic, the United States Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for manufactures and distributors of face masks that will remain in effect for the period of this public health emergency. Specifically, by issuing this EUA, the FDA recognized that there was an urgent need for more flexibility in the rules applicable to the manufacturing of face masks given the insufficient supply for use by health care personnel ("HCP") and the general public. Most importantly, by issuing this EUA, the FDA now allows health care providers to use EUA compliant face masks in their facilities even if the face masks do not constitute surgical masks and do not necessarily provide liquid barrier protection.

This EUA is much needed in that it will allow health care providers to prioritize the use of the scarce FDA-approved face masks for those HCPs in high risk areas for infection and allow face masks that comply with the EUA to be used by HCP in lower risk settings. This EUA also gives face mask manufacturers: (i) confidence to produce face masks without the need to necessarily comply with FDA's standard medical device approvals; and (ii) important guidance regarding product labeling and advertising.

To comply with the April 18, 2020 EUA for face masks, the authorized face masks must meet the following requirements:

1. 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).

2. 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 any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected, 3) for use in a clinical setting where the infection risk level through inhalation exposure is high; 4) for use in the presence of a high intensity heat source or flammable gas, 5) for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses, or 6) to include particulate filtration claims.

3. 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.

4. 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.

5. 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" [https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems] for reporting requirements and procedures.

6. 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.

7. 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.

8. 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:

1. 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.

2. 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.

3. 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 HCP as PPE to help prevent the spread of infection or illness in healthcare settings and by the general public to help slow the spread of the virus during the COVID19 pandemic; and

    - 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, 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.

Takeaways

The FDA's recent EUA is a useful and "common sense" development, however, healthcare providers and manufacturers alike must take heed to comply with the conditions of the EUA. Importantly, health care providers can conserve FDA-approved masks for sensitive surgical and high risk environments and use the face masks authorized by this EUA as PPE for lower risk environments. Further, manufacturers (including those just recently starting to produce face masks) must understand the above EUA conditions and prepare the appropriate language for the product and accompanying paperwork/packaging. Please also see our alert on tort immunity for manufacturers at https://shipmangoodwin.com/hhs-issues-advisory-opinion-regarding-prep-act-tort-liability-immunity-during-covid-19-pandemic. For questions, contact Joan Feldman at jfeldman@goodwin.com or Alfredo Fernandez at afernandez@goodwin.com.