Frequently Asked Questions from Industry for the FDA during the COVID-19 Pandemic

1. **What devices are eligible for an Emergency Use Authorization (EUA)?**
   A. On March 24, 2020, the Secretary of Health and Human Services "declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564" of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This declaration (https://www.fda.gov/media/136421/download) provides FDA with authority to issue an emergency use authorization (EUA) to any device that meets the EUA statutory criteria. We have granted EUAs to certain:

   - Ventilators
   - Personal Protective Equipment and a Decontamination Systems
   - In Vitro Diagnostics

   To see all the EUAs issued to date in the context of COVID-19, see the Emergency Use Authorizations page.

2. **What is the best way for a company to pursue an EUA?**
   A. If you would like to pursue an EUA or suggest a device type for an "umbrella" EUA, you should follow the instructions below.

   Manufacturers and other stakeholders interested in submitting an EUA request for an In Vitro Diagnostic should refer to How to Submit a Pre-EUA for In Vitro Diagnostics.

   Manufacturers and other stakeholders interested in submitting an EUA request for a Non-IVD Device may submit a request to the FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.

3. **What is the average turnaround time for the FDA to review and issue an EUA for a device?**
   A. In the context of the COVID-19 pandemic, FDA staff have been working to review and issue EUAs as soon as possible. Many device EUAs for the COVID-19 pandemic have been issued within days after receipt of a manufacturer's request.

4. **How is FDA working to facilitate the importation of devices, including personal protective equipment, during the COVID-19 pandemic?**
   A. Please refer to the Information for Filing Personal Protective Equipment and Medical Devices During COVID-19 provided by FDA to help facilitate the importation of products into the U.S. market to support the U.S. response to COVID-19. One of the FDA's priorities in combating the COVID-19 pandemic is to help facilitate access to critical personal protective equipment (PPE) and other

devices, and therapeutics. We are engaging with importers and others involved in the import trade community during this pandemic to help facilitate the entry of critical products, including PPE, into the United States.

5. **Would the FDA be willing to expand the types of devices currently included in the remote patient monitoring guidance, including for chronic conditions such as diabetes?**
   A. The FDA will expeditiously and carefully consider all inquiries or requests submitted to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov and comments to the guidance, Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency. We note that there are additional guidance documents that FDA has issued that address remote monitoring modifications during COVID-19 on certain devices such as infusion pumps, and certain ophthalmic devices. See a full list of FDA's COVID-19 related guidance documents here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

6. **What policies and EUAs has FDA issued regarding face masks and respirators with different intended uses, including masks for which the intended use is not for health care personnel use, masks for which the intended use is health care and for fluid barrier, and masks for which the intended use is health care but not having fluid barrier claims?**

   Currently, the FDA is taking steps to help expand the availability of face masks and respirators and believes the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) may help address the urgent public health concerns caused by shortages by taking a risk-based approach and outlining the FDA's policies for masks and respirators, including these products' associated indications and claims.

   Please refer to section V. Policy in the guidance and the following EUAs for respirators:

   - Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China
   - NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency
   - Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

7. **What policies has FDA issued regarding gowns, other apparel, and gloves?**
   A. Currently, the FDA is taking steps to help expand the availability of gowns and other apparel and believes the Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency may help address the urgent public health concerns caused by shortages by taking a risk-based approach and clarifying the FDA's policies for gowns and other apparel, including

these products' associated indications and claims. Please refer to the Policy for Gowns and Other Apparel section or the Policy for Gloves section of the guidance.

8. **What policies and EUAs has FDA issued regarding ventilators, ventilator accessories, and other respiratory devices?**
   A. The FDA has taken steps to increase the availability of ventilators to treat COVID-19 patients with respiratory failure or respiratory insufficiency. The guidance document, Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, describes policies to help increase the availability of critical devices including ventilators, anesthesia gas machines, and other respiratory devices, and their accessories. As noted in the guidance, wherever possible, health care facilities should use FDA-cleared conventional/standard full-featured ventilators when necessary to support patients with respiratory failure.

   As described in the guidance, to help ensure the availability of the greatest possible number of devices for this purpose, the FDA does not intend to object to limited modifications to the indications, functionality, or to the hardware, software, or materials of FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency, without prior submission of a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 807.81, for the duration of the declared public health emergency. This policy normally applies when a modification is made to the device that triggers the requirement that a manufacturer submit a new premarket notification (510(k)) to the FDA.

   In addition, the FDA has issued an EUA for ventilators, anesthesia gas machines modified for use as ventilators, positive pressure breathing devices modified for use as ventilators, and certain ventilator accessories. Products authorized under this EUA are listed in Appendix B: Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories.

9. **How is the FDA treating the use of 3D printing to manufacture devices such as ventilators and masks?**
   A. We recognize that the public may seek to use 3D printing to help meet demand for certain products during the COVID-19 pandemic. As part of our effort to protect the public to the extent possible, we have issued answers to frequently asked questions for entities who 3D print devices, accessories, components, and/or parts during the COVID-19 emergency.

10. **What additional immediately in effect guidance documents is the FDA contemplating?**
    A. The FDA will continue to take steps to help ensure the availability of critical medical devices and will expeditiously and carefully consider inquiries from industry sponsors, health care providers, and other stakeholders to assess if additional immediately in effect guidances are warranted. FDA staff and leadership are working around the clock

to assess potential needs and to issue needed new or expanded policies as soon as possible.

11. What recommendations does the FDA have for device manufacturing personnel in an environment of social distancing?

A. CDRH recognizes the challenges medical device manufacturers face in their effort to ensure the safety and well-being of their manufacturing personnel. The FDA has issued recommendations for Protecting the Health and Safety of Medical Device Manufacturing Personnel.

12. How will the FDA handle presubmission meeting requests during this time?

A. The FDA is unable to accommodate requests for in-person meetings but will still handle presubmission requests and schedule teleconferences, as requested. Specific requests related to COVID-19 are our highest priority.

Manufacturers and other stakeholders interested in submitting a pre-EUA request for a Non-IVD device may submit a request to the FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.

Manufacturers and other stakeholders interested in submitting a pre-EUA request for an IVD may submit a request to the FDA at CDRH-EUA-Templates@fda.hhs.gov.

13. What does the FDA expect in terms of a company meeting its postmarket obligations such as adverse event reporting?

A. The FDA's guidance, Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic describes the agency's recommendations regarding postmarketing adverse event reporting. In addition, product specific guidances issued during the COVID-19 pandemic may include additional recommendations about device-specific postmarket obligations.

14. Will the FDA identify whether devices are following the recommendations in these immediately in effect guidances in the FURLS database so that customers can easily find the device?

A. The list of the immediately in effect guidances is updated continuously on the COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders page. In some cases, to reduce the regulatory burden and facilitate marketing of needed products in the United States, the FDA has indicated in guidance that under certain circumstances, it does not intend to enforce certain requirements, including Registration and Listing requirements in 21 CFR Part 807. In those cases, a manufacturer may nevertheless decide to Register and List their product.

15. Will the FDA identify a device authorized by an EUA in the FURLS database so that customers can easily find the device?

A. All medical devices with an EUA, and their respective Letters of Authorization, are listed on the FDA's Emergency Use Authorizations page for quick access. This page is being updated continuously as new EUAs are issued.

16. What will the FDA's regulatory approach be to devices on the market after the emergency has ended?

A. The enforcement policies included in the immediately in effect guidances issued in response to the COVID-19 pandemic are intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the Secretary in accordance with section 319(a)(2) of the Public Health Service Act.

EUAs issued in response to the COVID-19 pandemic will be effective until the declaration that the circumstances justifying the authorization of the emergency use are terminated under section 564(b)(2) of the FD&C Act or the EUA is revoked under section 564(g) of the FD&C Act.

FDA will communicate transition plans appropriate for the circumstances at a future date.

17. What guidance has the FDA issued for the conduct of clinical trials during COVID-19?

A. On March 18, 2020, the FDA issued an immediately in effect guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic for industry, investigators, and institutional review boards conducting clinical trials during the coronavirus (COVID-19) pandemic. The guidance was updated on March 27, 2020 and April 2, 2020.