

On June 22, 2020, the U.S. Food and Drug Administration (FDA) issued a guidance to provide answers to frequently asked questions about regulatory and policy issues related to device development for devices regulated by the Center for Devices and Radiological Health (CDRH) as well as devices regulated by the Center for Biologics Evaluation and Research (CBER) during the COVID-19 public health emergency. Read the [Guidance](#).

## **Letter to Industry on COVID-19**

March 23, 2020

Dear Medical Device Establishments:

In response to the Coronavirus Disease 2019 (COVID-19) public health emergency,<sup>1</sup> FDA's Center for Devices and Radiological Health (CDRH) has taken the steps described in this letter to prioritize work that advances the nation's response during this national emergency.<sup>2</sup> These steps seek to address the impact of the COVID-19 public health emergency on day-to-day operations in CDRH and in the medical device industry, while ensuring that government and private sector efforts to respond to this national emergency receive the highest priority.

### **CDRH Has Converted In-Person Meetings with Industry to Teleconferences**

Where possible, CDRH is leveraging technology to host teleconferences rather than in-person meetings with industry scheduled through April 30, 2020. We are converting each meeting to a teleconference to be held at the same date and time. We believe we have contacted all parties with meetings scheduled through April 30, 2020 to provide teleconference information. If you have not received teleconference information, please reach out to the CDRH staff member who originally scheduled your meeting. We will continue to assess whether any in-person meetings scheduled later than April 30, 2020 should be converted to teleconferences and will provide periodic updates.

### **Processing of Incoming Documents**

The Document Control Center continues to receive and process incoming documents. In order to ensure the security of your information, we are generally unable to accept incoming submissions via email. In addition, existing systems have file size limitations associated with email. We are looking into electronic options other than email. We regret any delays this may cause you.

### **Extension of Response Due Dates for Marketing Applications Currently on Hold**

For marketing applications on hold as of March 16, 2020, where the response due date is on or before April 30, 2020, CDRH has extended response due dates by 60 days for Premarket Notifications (510(k)s), Premarket Approval (PMA) applications (original and supplements), Humanitarian Device Exemption (HDE)

applications (original and supplements) and De Novo classification requests. CDRH intends to extend this

due date automatically; no extension requests are necessary to be submitted.

For additional submission types where a response or report is due (e.g., Post Approval or 522 Study reports, Investigational Device Exemption annual reports, PMA reports), we encourage you to submit the response or report when possible.

Please address any questions about response due dates to [CDRHPremarketProgramOperations@fda.hhs.gov](mailto:CDRHPremarketProgramOperations@fda.hhs.gov).

### **How to Submit an Inquiry or Request for an Emergency Use Authorization**

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that involves the virus that causes COVID-19. On that same date, the Secretary declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 and on March 4, 2020, the Secretary made the declaration with respect to personal respiratory protective devices. Under FDA's emergency use authorities, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in certain emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives. We strongly encourage applicants to submit pre-EUAs to discuss technologies that might help address this emergency.

More information about [current EUAs](#) is on the FDA's Emergency Use Authorization web page.

For inquiries related to EUAs for in vitro diagnostics (IVDs), contact [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov)

For inquiries related to EUAs related to non-IVD medical devices, contact [CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov](mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov)

For more information about the EUA program, please see the guidance, [Emergency Use Authorization of Medical Products and Related Authorities](#).

### **COVID-19 Related Guidance Documents**

FDA has issued immediately in effect guidance documents related to COVID-19. For the latest information, please see the [FDA's COVID-19 Related Guidance Documents web page](#).

### **Postmarket and Compliance Activities**

CDRH continues to process and work on mission critical post-market and compliance activities.

Medical devices play an essential role in advancing public health in the response to the COVID-19 national emergency. As such, our work in supporting the availability of critically-needed medical devices is our highest priority.



If you have any questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at [DICE@FDA.HHS.GOV](mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100.

Sincerely,

/s/

William Maisel, MD, MPH  
Director, Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

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<sup>1</sup> On January 31, 2020, the Secretary of Health and Human Services Alex M. Azar, issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>).

<sup>2</sup> On March 13, 2020, the President declared a national emergency in response to COVID-19. President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).