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.

Updated Letter to Industry on COVID-19

April 4, 2020

Dear Medical Device Establishments:

In response to the Coronavirus Disease 2019 (COVID-19) public health emergency, the 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. These steps address the impact of the pandemic 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. This letter serves as an update to the policies first communicated in the March 23, 2020 "Letter to Industry."

CDRH Has Further Extended the Conversion of 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 May 31, 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 May 31, 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 May 31, 2020 should be converted to teleconferences and will provide periodic updates.

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 June 30, 2020, CDRH has further extended response due dates by 90 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.

COVID-19 Related Guidance Documents

FDA has issued additional 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.

If you have any questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at 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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