

Contains Nonbinding Recommendations

Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices — Questions and Answers (Revised)

Guidance for Industry and Food and Drug Administration Staff

**June 2020
Updated December 2020**

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Center for Biologics Evaluation and Research (CBER)**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA web page titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders> and the FDA web page titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20040-R1 and complete title of the guidance in the request.

Questions

For questions about this document, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100. For questions specific to CBER, please contact CBER at CBER_COVID19_Regulatory_Questions@fda.hhs.gov.

Table of Contents

I.	Introduction.....	1
II.	Background	2
III.	Questions and Answers	3
A.	Meetings with Industry.....	3
B.	MDUFA Goals and Timelines.....	4

Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices — Questions and Answers (Revised)

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide answers to frequently asked questions about regulatory and policy issues related to device¹ development for the duration of the COVID-19 public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in

¹ The term “device(s)” in this document refers to devices regulated by CDRH as well as devices regulated by CBER, including devices regulated as biological products under Section 351 of the Public Health Service (PHS) Act.

Contains Nonbinding Recommendations

accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

In general, FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2,” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.² In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.³

FDA recognizes that the COVID-19 public health emergency is affecting the public health in numerous direct and indirect ways, including effects on device development programs. FDA also recognizes that submitters and applicants have many regulatory questions related to these effects. Therefore, FDA has developed this guidance to provide answers to frequently asked questions.

Regulated industry should continue to monitor the FDA website and public statements for guidance and direction.⁴

² Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists (originally issued on Jan. 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

³ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

⁴ See, e.g., <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>; Letters to Industry (<https://www.fda.gov/medical-devices/industry-medical-devices/letters-industry>).

III. Questions and Answers

A. Meetings with Industry

Q1. What specific plans does FDA have in place to hold previously scheduled meetings associated with submission or application reviews and/or timelines?

A1. FDA is leveraging technology to host teleconferences and videoconferences rather than in-person meetings with industry during the COVID-19 public health emergency. Until further notice, all requests for in-person meetings will be handled as requests for teleconferences, and all CDRH meetings previously scheduled as in-person meetings have been converted to teleconferences to be held at the same date and time. CBER may use teleconference or videoconference meeting formats.⁵

The CDRH Offices of Health Technology (OHTs) and the applicable CBER Offices⁶ have reached out to communicate this change in format to all submitters or applicants with meetings previously scheduled to provide updated meeting information. If you are a submitter or applicant and have not received teleconference information, please reach out to the FDA staff member who originally scheduled your meeting. Submitters and applicants with questions regarding their scheduled meetings should contact the appropriate CDRH OHT or CBER Office directly.

Q2. As submitters and applicants continue to submit Q-submission requests, what are FDA’s plans to accept new Q-submission requests and provide submitters or applicants with options for alternative meeting formats?

A2. FDA is continuing to accept new Q-submission requests. Q-submission requests for CDRH and CBER meetings are currently being scheduled as teleconference meetings⁷ or, when requested by the sponsor, FDA is providing a written response only.

Q3. Does FDA plan to conduct upcoming advisory committee meetings virtually?

A3. FDA can host advisory committee meetings virtually with current technology. The CDRH OHTs and CBER Offices will work closely with submitters and applicants for specific

⁵ As described in the CDER/CBER guidance entitled “[Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-questions-and),” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-questions-and>).

⁶ In CBER, regulatory project managers (RPMs) are assigned to Offices and would have reached out to communicate the change in format. Please see the FDA guidance from the Center for Drug Evaluation and Research (CDER) and CBER entitled “[Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-questions-and)” for more information on RPMs and CBER communications (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-questions-and>).

⁷ CBER may also utilize videoconference meeting formats.

Contains Nonbinding Recommendations

submissions or applications that could potentially be affected and will discuss options for pursuing teleconference or videoconference (live virtual) meetings.

In addition, advisory committee meetings regarding regulatory issues, such as classification/reclassification or general issues,⁸ may also proceed virtually and may be identified as such in any related Federal Register Notice announcing the meeting. A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/advisory-committees> and scroll down to the appropriate advisory committee meeting link for the most updated information.

B. MDUFA Goals and Timelines

Q4. Will some MDUFA submissions or applications be delayed because of the COVID-19 public health emergency?

A4. FDA remains committed to the Medical Device User Fee Amendments (MDUFA) performance goals.⁹ However, we are experiencing considerable increases in COVID-19 activities related to pre-Emergency Use Authorizations (pre-EUAs), EUAs, and the development of policies, requiring shifting of staff resources to focus on these critical activities. The COVID-19 public health emergency also has other effects on our resources such as deployments of staff who are members of the U.S. Public Health Service Commissioned Corps. With many staff members working on COVID-19 activities and activities with statutory deadlines, it is possible that we will not be able to sustain our current performance levels indefinitely. Should an Original premarket approval application (PMA), panel track PMA supplement, premarket notification [510(k)] submission, or De Novo request miss its MDUFA performance goal, FDA will follow the missed MDUFA decision procedures outlined in the guidance documents "[FDA and Industry Actions on Premarket Approval Applications \(PMAs\): Effect on FDA Review Clock and Goals](#),"¹⁰ "[FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](#),"¹¹ and "[FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals](#)."¹²

⁸ For additional information regarding the types of regulatory issues that FDA may refer to an advisory committee, see FDA's guidance "Procedures for Meetings of the Medical Devices Advisory Committee" at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-meetings-medical-devices-advisory-committee>

⁹ MDUFA IV Performance Goals and Procedures, Fiscal Years 2018 through 2022 (MDUFA IV Commitment Letter), available at <https://www.fda.gov/media/102699/download>.

¹⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals>

¹¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals>

¹² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals>

Contains Nonbinding Recommendations

Q5. Will the goal dates be extended because of the COVID-19 public health emergency?

A5. We are committed to working to meet the performance goals outlined in the MDUFA commitment letter.¹³ However, with many staff members working on COVID-19 activities and activities with statutory deadlines, we may not be able to maintain our current level of performance with respect to the performance goals and associated timelines in our user fee commitments. The MDUFA commitment letter does not contemplate FDA extending or changing user fee goal dates, except in certain instances like following submission of an unsolicited major amendment that would allow for a clock extension. If FDA anticipates missing a MDUFA goal date because of the current public health emergency, we plan to communicate with the submitter or applicant directly. In addition, we will follow the procedures for missed MDUFA decisions outlined in the guidance documents entitled “[FDA and Industry Actions on Premarket Approval Applications \(PMAs\): Effect on FDA Review Clock and Goals](#),” “[FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](#),” and “[FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals](#).”

Q6. What is FDA’s policy for marketing submissions or applications currently on hold?

A6. For marketing submissions or applications on hold, FDA generally considers the submission or application to be withdrawn if the submitter or applicant does not provide a complete response to major deficiency letters for PMA (original and supplements)¹⁴ and Humanitarian Device Exemption (HDE) applications (original and supplements)¹⁵ within 360 days or to additional information letters for 510(k)s¹⁶ and De Novos requests¹⁷ within 180 days. Given the COVID-19 public health emergency, we recognize that applicants may face challenges affecting their ability to meet their applicable response date, and FDA may be unable to process a high volume of individual extension requests on a timely basis. In light of these considerations, for marketing submissions and applications on hold where the response date is on or before the date this guidance is withdrawn, FDA does not intend to consider a submission or application to be withdrawn for an additional 180 days beyond the relevant response date.

¹³ MDUFA IV Performance Goals and Procedures, Fiscal Years 2018 through 2022 (MDUFA IV Commitment Letter), available at <https://www.fda.gov/media/102699/download>.

¹⁴ For more information, please see the FDA guidance document entitled “[FDA and Industry Actions on Premarket Approval Applications \(PMAs\): Effect on FDA Review Clock and Goals](#)” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals>)

¹⁵ For more information, please see the FDA guidance document entitled “[Humanitarian Device Exemption \(HDE\) Program](#)” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program>).

¹⁶ For more information, please see the FDA guidance document entitled “[FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](#)” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals>).

¹⁷ For more information, please see the FDA guidance document entitled “[FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals](#)” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals>).

Contains Nonbinding Recommendations

This policy regarding response dates is intended to apply to the marketing submissions and applications described above regardless of whether the applicant submits an extension request or not and does not require the submission of an extension request.

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), if you are unable to submit the response or report by the due date because of challenges related to COVID-19, we encourage you to submit the response or report as soon as possible. Please address any questions about response due dates to OPEQSubmissionSupport@fda.hhs.gov for CDRH or CBER_COVID19_Regulatory_Questions@fda.hhs.gov for CBER.

Q7. In the event that Biologics License Application (BLA) goal dates for devices licensed under the Public Health Service Act are not able to be met because of the COVID-19 public health emergency, how will CBER communicate these missed dates to applicants?

A7. As with other products subject to MDUFA, we are committed to working to meet the performance goals outlined in the MDUFA commitment letter for BLA devices. However, with many staff members working on COVID-19 activities, we may not be able to maintain our level of performance with respect to the performance goals and associated timelines in our user fee commitments. Should a device regulated by CBER as a biological product under Section 351 of the PHS Act miss its MDUFA performance goal, CBER will communicate with the submitter or applicant directly.

Please refer to the Agency's existing guidance documents on making changes to a BLA. If an applicant wishes to discuss flexible submission strategies for changes because of circumstances resulting from the COVID-19 pandemic for a CBER-regulated device, we recommend contacting the Office responsible for the product's regulation for further assistance.

Q8. What additional guidance has FDA provided about COVID-19?

A8. The FDA has issued additional immediately in effect guidance documents related to COVID-19. For the latest information, please see [FDA's COVID-19 Related Guidance Documents web page](#).¹⁸

¹⁸ <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>