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Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers

Guidance for Industry

May 2020

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
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-1136 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/mcm-issues/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 COVID19-productdevelopment@fda.hhs.gov to receive an additional copy of the guidance. Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

Questions

For questions about this document, contact CDER at ONDCommunications@fda.hhs.gov and CBER at CBERCOVID19RegulatoryQuestions@fda.hhs.gov.

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Guidance for Industry

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 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 drug 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 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented

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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.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

FDA recognizes that the COVID-19 public health emergency is affecting the public health in numerous direct and indirect ways, including effects on drug development programs. FDA also recognizes that sponsors and applicants have many regulatory questions related to these effects. Therefore, FDA has developed this guidance to provide answers to frequently asked questions.³

Regulated industry should continue to monitor the FDA website and public statements for guidance and direction. Application holders should continue to notify the appropriate center regarding potential drug and biologic shortages through the Center for Drug Evaluation and Research (CDER) Drug Shortages Program⁴ or for the Center for Biologics Evaluation and Research (CBER) at CBERshortage@fda.hhs.gov.

¹ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists (Jan. 31, 2020, renewed April 21, 2020), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

² 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/>.

³ FDA also encourages regulated industry to refer to the guidance for industry *Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products* (March 2011), which provides information for manufacturers of medically necessary drug products and any components of those drug products on developing contingency production plans to use during emergencies that result in high absenteeism at production facilities. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

⁴ See the Drug Shortages web page at <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>.

III. QUESTIONS AND ANSWERS

A. Formal Meetings with Industry under PDUFA and BsUFA

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

A1. CDER and CBER are leveraging technology to host virtual meetings rather than in-person meetings with industry during the COVID-19 public health emergency. At this time all meetings will be held virtually.⁵ Many Prescription Drug User Fee Act (PDUFA) or Biosimilar User Fee Act (BsUFA) meetings that were previously scheduled as in-person meetings have been converted to virtual meetings to be held at the same dates and times as the originally scheduled meetings. The review divisions' regulatory project managers (RPMs) have reached out to communicate this change in format to all parties with meetings previously scheduled to obtain virtual meeting information.⁶ Sponsors and applicants with questions regarding their scheduled meetings should contact the appropriate review division's RPM directly.

Q2. As sponsors and applicants continue to submit meeting requests, what are FDA's plans to accept new meeting requests and provide sponsors or applicants with options for alternative meeting formats?

A2. FDA is continuing to accept new meeting requests, and in general, we are granting these meetings as per usual practice outlined in the draft guidances for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (December 2017) and *Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products* (June 2018).⁷ Meetings are currently being scheduled as virtual meetings or, when appropriate, as written response only. As circumstances warrant, we intend to re-evaluate the format of individual meetings that are still pending.

To ensure that virtual meetings go as smoothly as possible, we are disseminating best practices and providing training to FDA staff for meeting management. For additional assistance with effective meeting management during this time, we encourage sponsors and applicants to work with their review divisions' RPMs directly.

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

A3. FDA is continuing to evaluate the feasibility of conducting advisory committee meetings virtually. We believe we can host advisory committee meetings virtually with current technology. The review divisions will work closely with sponsors and applicants for specific

⁵ Virtual meetings refer to meetings using a teleconference or videoconference format.

⁶ In CBER, RPMs are assigned to offices.

⁷ When final, these guidances will represent the FDA's current thinking on these topics. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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applications that could potentially be affected and will discuss options for pursuing virtual meetings.

B. PDUFA and BsUFA Goals and Timelines

Q4. Will some PDUFA and BsUFA applications be delayed because of the COVID-19 public health emergency?

A4. The New Drugs Program in CDER, and the Biologics Program in CBER are experiencing considerable increases in COVID-19 related work, requiring shifting of staff resources to help with these 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, it is possible that we will not be able to sustain our current performance level in meeting goal dates indefinitely. We anticipate that the New Drugs Program and the Biologics Program may need to allocate resources to focus on certain activities. We intend to focus resources on investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) (both 351(a) and 351(k) applications) for drugs or biologics related to COVID-19 or certain other life-threatening conditions. Exceptions include the initial IND 30-day safety review and other important safety issues that may emerge during IND development. We will continue to work directly with the sponsors and applicants regarding their pending applications.

Q5. Does FDA expect that PDUFA and BsUFA goal dates will be missed, or 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 PDUFA VI and BsUFA II goals letters.⁸ 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. The PDUFA and BsUFA goals letters do not contemplate FDA extending or changing user fee goal dates, except in certain instances like following submission of a major amendment that would allow for a clock extension. If FDA anticipates missing a PDUFA or BsUFA goal date because of the current public health emergency, we will communicate with the sponsor or applicant directly.

C. GDUFA Goals and Timelines

Q6. Does FDA anticipate COVID-19 affecting its ability to maintain its performance levels, specifically with respect to meeting Generic Drug User Fee Act (GDUFA) metrics and goal dates?

A6. The COVID-19 public health emergency has affected some activities, such as travel and inspections; however, FDA is continuing Generic Drug Program application assessment

⁸ See PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 (PDUFA VI goals letter”), available at <https://www.fda.gov/media/99140/download> and Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 (BsUFA II goals letter), available at <https://www.fda.gov/media/100573/download>.

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activities. As FDA identifies more potential generic drug shortages, we may need to shift resources to address urgent public health needs.

Q7. In the event goal dates are not able to be met because of the COVID-19 public health emergency, how will FDA communicate these missed dates to applicants?

A7. If generic drug applicants experience a missed goal date, they should reach out to the appropriate project manager. For unapproved abbreviated new drug applications (ANDAs), the appropriate project manager is the RPM. For supplements to ANDAs, applicants should contact the appropriate discipline project manager if the supplement pertains to one discipline, or the RPM for multidisciplinary supplements.

Q8. What are FDA's contingency plans related to cancellation of meetings associated with application reviews and/or GDUFA timelines?

A8. Mid-review cycle meetings and post-complete response letter meetings are conducted by teleconference in the normal course and will continue in this format. Face-to-face pre-ANDA meetings are being converted to teleconferences. FDA will monitor meeting dates and intends to notify an applicant at least 4 weeks in advance if a meeting format is being converted.

Q9. If an ANDA applicant or an approved ANDA holder seeks information from the FDA related to regulatory activities affected by the COVID-19 public health emergency, who should the applicant or application holder contact?

A9. For approved and unapproved ANDAs, the contact is the RPM.

Q10. If an ANDA applicant or an approved ANDA holder seeks information from FDA related to general regulatory questions not specific to an ANDA, who should the applicant or application holder contact?

A10. Applicants and application holders should submit general inquiries to DrugInfo@fda.hhs.gov.

Q11. How is FDA prioritizing the review of ANDAs under GDUFA during the COVID-19 public health emergency?

A11. Recognizing the public health emergency related to COVID-19 declared by the HHS Secretary, FDA is prioritizing the review of ANDA submissions that could help address COVID-19. CDER's Manual of Policies and Procedures 5240.3 Rev.5 *Prioritization of the Review of Original ANDAs, Amendments, and Supplements* describes public health priorities (or prioritization factors) that may qualify an ANDA for a priority review. One factor considers whether the submission could help address a declared public health emergency. As part of its evaluation of whether a submission could help address the current public health emergency, FDA will consider whether the ANDA is (1) for a drug being investigated to treat or prevent COVID-19, but is not labeled for this use, or (2) for a drug being used for its labeled use to treat or prevent secondary conditions associated with COVID-19.