Letter to Sponsors, Applicants and Regulated Entities on COVID-19

June 9, 2022 (update of April 30, 2020 letter)

In response to the Coronavirus Disease 2019 (COVID-19) public health emergency[1], FDA's Center for Biologics Evaluation and Research (CBER) took the steps described in the letter of April 30, 2020 posted on the CBER website to prioritize work that advances the nation's response during this national emergency.[2] These steps sought to address the impact of the COVID-19 public health emergency on day-to-day operations in CBER and industry, while ensuring that government and private sector efforts to respond to this national emergency receive the highest priority. **This letter clarifies and updates CBER operations from those described in the letter issued on April 30, 2020.**

The impact of COVID-19 on CBER during the public health emergency has been unprecedented and placed extreme burdens on product development, approval, and surveillance functions. Although COVID-19 workload has been reduced in some areas, there remains substantial COVID-19 regulatory work, especially for vaccines. In addition, CBER's non-COVID-19 review workload continues to remain substantial, especially in non-COVID-19 vaccines and in cellular and gene therapies. For the remainder of this calendar year, CBER will continue to prioritize resources for COVID-19 regulatory work over non-COVID-19 work, as needed, to respond to the ongoing public health emergency. As we enter calendar year 2023, we plan to resume normal operations.

CBER Meetings

Starting in April 2020, CBER leveraged technology to convert all applicant and sponsor in-person meetings to virtual meetings. Currently, all external meetings remain in virtual format. CBER will continue to assess the feasibility of holding in-person meetings at FDA facilities. Sponsors and applicants should monitor the CBER website for updates regarding in-person meetings.

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[1] 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).

[2] 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/presidentialactions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

Processing of Incoming Documents and CBER Responses

The CBER Document Control Center (DCC) will process paper and electronic media (CD/DVD, USB drive, etc.) submissions sent via U.S. mail or courier **effective immediately.**

Paper and physical media submissions should be sent to:

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71, G112
Silver Spring, MD 20993-0002

Commercial applicants and sponsors should continue to submit in standard eCTD format using the ESG as described in guidance for industry, Providing Regulatory Submission in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.

CBER prefers those submissions not subject to the 745(A) binding guidance and CBER Applications Submissions Guidance be sent in the following manner (in order of preference):

- FDA Electronic Submission Gateway
- CBER submission email box (150MB max): CBERDCC_eMailSub@fda.hhs.gov
- Electronic media (USB drive, DVD/CD) with no paper components
- Paper submissions

As always, the following can be sent via non-secure e-mail; Requests for Individual Patient INDs under Expanded Access, including for emergency use; Compassionate Use IDEs; Requests for Emergency Use Authorizations (EUAs) and Pre-EUAs; Emergency alternative procedures or exemptions under 21 CFR 640.120; and requests for information that are general in nature. Requests for Expanded Access and Compassionate Use IDEs can be made by phone.

Regulatory communications from CBER to sponsors and applicants will generally be sent via secure e-mail. To establish secure email, please follow the instructions in SOPP 8119 *Use of Email for Regulatory Communications,* Appendix A.

Extension of Response Due Dates for Device Marketing Applications Currently on Hold

FDA announced in the Federal Register on June 7, 2022, the withdrawal of the guidance document entitled "Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (Revised)," which was issued in June 2020 (and updated December 2020). This guidance automatically extended applicant response due dates to address many device submission deficiencies. FDA is withdrawing this guidance document in recognition that the conditions that created the need for these policies have evolved, such that these policies are no longer needed. This action will facilitate more timely premarket review of innovative and potentially lifesaving devices. The withdraw date is effective July 7, 2022.

COVID-19 Related Guidance Documents

FDA has issued guidance documents related to COVID-19. For the latest information, please see the FDA's COVID-19 Related Guidance Documents web page.

Conduct of Clinical Trials involving Medical Products

The COVID-19 pandemic may impact the conduct of clinical trials and could result in protocol modification or unavoidable product deviations. Please see FDAs Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic for general guidance. Questions on specific clinical trials should be directed to the assigned product office.

Postmarket and Compliance Activities

CBER continues to process and work on post-market and compliance activities.

In response to the ongoing COVID-19 pandemic, CBER paused certain lot release activities beginning on March 23, and will not be receiving biological product samples or protocols *in physical form* (paper or CD-ROM) until further notice. Please see March 17, 2020 Letter to Manufacturers: Updated Instructions for Submitting Lot Release Samples and Protocols During the COVID-19 Pandemic. Applicants should monitor the CBER website for updates regarding lot release activities.

How to submit an Inquiry for a Single Patient IND or Request for an Emergency Use Authorization

FDA is committed to doing everything we can to provide timely response efforts to the pandemic and facilitate access to investigational drugs for use in patients with serious

or immediately life-threatening COVID-19 infections. For additional information on gaining access to investigational drugs see Expanded Access.

For information on Emergency Use Authorization (EUA) see Emergency Use Authorization . For questions on the EUA process, please contact CBEREUA@fda.hhs.gov.

CBER regulated products continue to 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 products is our highest priority.

If you have any questions about this communication, please contact the Office of Communication, Outreach and Development via email at Industry.Biologics@fda.hhs.gov, 240-402-8010, or 800-835-4709.

Sincerely,

/s/

Christopher C. Joneckis, PhD
Associate Director for Review Management
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration