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

April 30, 2020 (update of April 24, 2020 letter)

In response to the Coronavirus Disease 2019 (COVID-19) public health emergency,[1] FDA's Center for Biologics Evaluation and Research (CBER) has taken the steps described in this letter to prioritize work that advances the nation's response during this national emergency.[2] These steps seek 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 24, 2020**

## CBER Has Converted In-Person Meetings with Industry to Teleconferences

CBER is leveraging technology to host teleconferences rather than in-person meetings with industry scheduled through May 29, 2020. We are converting each meeting to a teleconference to be held at the same date and time. We will contact all parties with meetings scheduled through May 29, 2020 to provide teleconference information. If you have not received teleconference information two weeks prior to your scheduled meeting date, please reach out to the CBER staff member who originally scheduled your meeting. We will continue to assess whether any in-person meetings scheduled later than May 29, 2020 should be converted to teleconferences and will provide periodic updates.

## Processing of Incoming Documents and CBER Responses

The Document Control Center (DCC) will not process any submissions received by mail or courier including submissions provided on paper and electronic media (e.g., CDs, USB drives) after Wednesday, April 29, until further notice. Submission previously submitted by mail can still be sent through the Electronic Submission Gateway (ESG) or in some cases by e-mail. CBER strongly encourages sending submissions (under 10GB) through FDA's preferred secure method of transmission, the ESG. 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.

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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/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

Applicants and sponsors exempt from eCTD submission requirements (e.g., research[3]) may submit a PDF version to the DCC via email at CBERDCC_eMailSub@fda.hhs.gov. However, we draw your attention to the option of submission via the ESG using the alternate (non-eCTD) format, as described in draft guidance Providing Regulatory Submissions in Alternate Electronic Format. Device submissions, for CBER regulated devices, should be submitted in accordance with final industry guidance, eCOPY Program for Medical Devices Submissions.

Applicants and sponsors of biological product submissions that are exempt from eCTD requirements, as well as applicants and sponsors of device submissions who are experiencing difficulty sending submissions using the preferred secured methods, or do not have an ESG account may send submissions (under 150MB) via email at CBERDCC_eMailSub@fda.hhs.gov. We will accept these submissions through this email option only during the COVID-19 public health emergency.

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**

For device marketing applications on hold as of March 16, 2020, where the response due date is on or before April 30, 2020, CBER has 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. CBER intends to extend this due date automatically; no extension requests are necessary to be submitted.

For additional device 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.

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[3] When a sponsor that generally submits Research INDs, then submits either a Phase 2 or Phase 3 protocol, they should select "Commercial" (eCTD requirements will apply). However, when the sponsor believes the Phase 2 or Phase 3 protocol is still solely for research, the sponsor may submit a justification explaining their rationale in the cover letter, along with the protocol. If the FDA agrees, then the IND will remain a "Research" IND and the eCTD requirements will not apply. Note that in all cases, expanded access INDs and protocols should be marked as "Research" on the Form 1571 and are exempt from eCTD requirements. [From Instructions For Filling Out Form FDA 1571]

Please address any questions about response due dates directly to the assigned product office.

**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.

**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 mission critical 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.

**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.

One investigational treatment being explored for COVID-19 involves the use of convalescent plasma collected from recovered COVID-19 patients. Healthcare providers interested in the emergency use of investigational COVID-19 convalescent plasma under a single patient emergency IND should review FDA's webpage, Investigational COVID-19 Convalescent Plasma - Emergency INDs, for considerations about COVID-19 convalescent plasma, including information on how to obtain authorization.

Under FDA's emergency use authorities, the FDA Commissioner may permit the use of unapproved medical products or unapproved uses of approved medical products 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 encourage applicants to submit any questions to CBEREUA@fda.hhs.gov.

CBER regulated products 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 Communications, 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