FOLEY HOAG LLP

FDA Alert

FDA Will Facilitate Biological Product Development Against COVID-19

Written by Paul T. Kim, Areta Kupchyk

April 2, 2020

The U.S. Food and Drug Administration (FDA) announced in a March 27, 2020 letter to industry that the Center for Biologics Evaluation and Research (CBER) has implemented new measures to prioritize biological product development and review to accelerate the nation's response to the COVID-19 public health emergency.

Highlights of CBER Measures

- CBER has **converted its in-person meetings** scheduled through April 30, 2020 to teleconferences, where possible, and will assess whether meetings scheduled later than April 30, 2020 also should be converted to teleconference.
- CBER has **extended the response due date** for medical device marketing applications that relate to biological products and are subject to CBER review.Applications that were on hold as of March 16, 2020 and had a response due to the agency before April 30, 2020 will receive an automatic 60-day extension.
- CBER has **paused certain lot release activities** and has ceased to receive biological product samples in physical form until further notice.
- FDA has developed a procedure to provide interested healthcare providers with **emergency use of investigational convalescent plasma.**
- CBER **encourages industry to send submissions** through FDA's Electronic Submission Gateway using the agency's standard procedures.

Vaccine Pre-IND Submissions

In communications to potential vaccine sponsors interested in meeting to discuss vaccine development for COVID-19/SARS-CoV-2, CBER has requested that potential sponsors submit a pre-IND Written Responses Only (WRO) meeting request and the background package via the Gateway. The Office of Vaccines Research and Review (OVRR) will provide written responses with the possibility of a teleconference if additional clarification is necessary. Because CBER seeks to expedite its response for the development of COVID-19 vaccines, CBER requests that sponsors provide a brief timeline of their clinical/product development plan.

FDA has also issued a number of COVID-19 related guidance documents in recent weeks, including guidance for the conduct of clinical trials of medical products during the pandemic. Foley Hoag is advising clients on these and other issues in engaging FDA for COVID-19 product development.

Foley Hoag has formed a firm-wide, multi-disciplinary task force dedicated to client matters related to the novel coronavirus (COVID-19). For more guidance on your COVID-19 issues, visit our Resource Page or contact your Foley Hoag attorney.

RELATED INDUSTRIES

- Life Sciences
- Healthcare

RELATED PRACTICES

- COVID-19 Task Force
- FDA

- Life Sciences Coverage & Payment
- Healthcare