

submissions provided on paper and electronic media (e.g., CDs, USB), until further notice. Device submissions, for CBER regulated devices, can still be submitted electronically using the Electronic Submissions Gateway (ESG) (under 10GB) or in some cases via email (under 150MB) in accordance with final industry guidance, eCOPY Program for Medical Devices Submissions found at <https://www.fda.gov/media/83522/download>. CBER strongly encourages sending submissions through the ESG, FDA's preferred secure method of transmission. Instructions for setting up an ESG account can be found at <https://www.fda.gov/industry/electronic-submissions-gateway>.

Submissions regarding this file may also be submitted electronically via email at CBERDCC_eMailSub@fda.hhs.gov. We will accept submissions through this email option only during the COVID-19 public health emergency. For additional information regarding CBER operations during this public health emergency, please see the CBER COVID -19 CBER Regulated Biologics page found at <https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics>.

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

Hira Nakhasi, PhD
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