



Date: June 17, 2021

From: Christopher Joneckis, Associate Director For Review Management

Subject: Issuance of BLA License Number in Advance of Approval

To: STN 125742, COVID-19 mRNA Vaccine

I am authorizing release of the BLA license number for Pfizer/ BioNtech Covid vaccine in advance of the typical notification in the approval letter. A significant consideration in this decision is that this product has been authorized under an Emergency Use Authorization, and therefore CBER is familiar with and has reviewed much of the information provided in the BLA application. This deviation from our normal practice is done to facilitate product labeling and distribution and is consistent with other Center practices to facilitate vaccine delivery during the declared Public Health Emergency. When providing the license number, we should communicate that this license number does not constitute any determination by FDA on the application.